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CANCER DETECTION IN WOMEN

HEARING

BEFORE THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

SECOND SESSION

ON

REVIEWING PROCEDURES FOR CANCER DETECTION IN WOMEN, FOCUSING ON MAMMOGRAPHY AND THE EARLY DETECTION OF BREAST CANCER, AND PROBLEMS IN THE MEDICAL TESTING INDUSTRY CONCERNING PAP TESTS

JANUARY 28, 1988

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CANCER DETECTION IN WOMEN

THURSDAY, JANUARY 28, 1988

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The Committee convened, pursuant to notice, at 10:02 a.m., Senator Barbara A. Mikulski, presiding.

Present: Senators Mikulski and Adams.

Senator MIKULSKI (presiding). The Committee will come to order. I am going to ask that our first two witnesses come up to the table before I start my opening statement. We want to give them a particularly warm welcome.

Rose Kushner has been a long-time advocate in this area; and Jill Ireland, who has very graciously volunteered her own time to be here for this most important issue.

Ms. Ireland, the Committee welcomes you. I am going to say a few words to set the purpose of the hearing and to open the hearing, and then we will move to your testimony, and certainly to you, Ms. Kushner. The Committee welcomes everyone.

OPENING STATEMENT OF SENATOR MIKULSKI

Senator MIKULSKI. I am pleased to welcome everyone to the Senate Labor and Human Resources Committee hearing on Cancer Detection in Women. The hearing is essentially going to have two parts. The first part will focus on the crucial role that mammography screening plays in early detection and cure of breast cancer, particularly among us older women. The second part will examine the Pap smear industry and how much confidence we should have in the results of those tests.

First, on the subject of breast cancer. Breast cancer strikes one out of ten women in America. It is the most common form of cancer among women, and until 1986, it was the leading cause of death from cancer in women.

Each year, 40,000 women die from breast cancer. More than half of them are 65 years or older. And post-menopausal women are particularly vulnerable to this. Thousands more will undergo extensive surgery, often radical mastectomies.

I am 52 years old, and I went to a very small high school of only 120 girls—an all women's school. Two of my classmates have already died of breast cancer. Had mammography been available earlier, had been more reliable earlier, perhaps my two classmates would be joining our reunion this May.

The premature death of a woman from cancer is always tragic, yet the greatest tragedy of all is that many of these deaths could have been prevented if the cancer had been detected earlier, if we had had the technology to detect breast cancer when it is still in its early stages.

Mammography is a highly safe and reliable procedure which now can detect tumors before they can be felt, when the chances of cure are over 90 percent. Yet very few women undergo regular mammography screening.

Last year, 24,000 women over the age of 65 died of breast cancer. It is estimated that fewer than 10 percent of these women had any type of mammograms on a regular basis.

One primary reason for that is the cost of a mammogram can run as high as $200—a tremendous burden for a woman on Social Security, who is worrying about paying her heating bills, buying her food, or quite frankly, paying for her prescription drugs.

My own home State of Maryland is only one of four States that mandate any sort of insurance coverage for mammography screening. Yet there are 16 million women older than 65 in this country. We must do more.

That is why I have introduced legislation to enable Medicare recipients to benefit from this well-proven screening technique. Last year, we passed legislation making a patient's expenditure for mammography count toward their medical deductible. My bill provides actual Medicare reimbursement for a mammogram every other year. It has a built-in cost containment feature because it caps the reimburseable cost at $50 and mandates something on an assignment basis. This prevents additional cost from being passed on to the consumer.

I believe that no woman should have to experience the devastating effect of breast cancer simply because she cannot afford to have routine screening. My legislation is an important first step in ensuring this.

I know that all America worried about Mrs. Reagan as she faced her own situation. What I want to do, though, is make available to other senior citizen women at no cost the same type of care made available to the First Lady. That really will be the first part of our hearing, and then the second part will move on to the issue of Pap smears. Just a word about that before we turn to our witnesses.

Every woman in America knows that she faces a fatal disease when it comes to cervical cancer. Practically every woman in America now relies on a Pap smear to give her her early warning system. However, we now find that the lab tests can be as deadly in their misdiagnosis as the disease itself.

When properly conducted, the Pap smear is the best-known, reliable, accurate test for cervical cancer. However, we have reports of misdiagnosis up to 20 or 40 percent of Pap smears because of poor laboratory testing. This sends a chilling message to women everywhere: Do not trust the results of this test on which so many women's lives depend.

[The full text of Senator Mikulski's opening statement follows:]

OPENING STATEMENT OF SENATOR BARBARA A. MIKULSKI
HEARING ON CANCER DETECTION IN WOMEN
JANUARY 28, 1988

I AM PLEASED TO WELCOME EVERYONE TO THIS SENATE LABOR AND HUMAN RESOURCES COMMITTEE HEARING ON CANCER DETECTION IN WOMEN. THIS HEARING WILL HAVE TWO PARTS. THE FIRST PART WILL FOCUS ON THE CRUCIAL ROLE MAMMOGRAPHY SCREENING PLAYS IN THE EARLY DETECTION AND CURE OF BREAST CANCER, PARTICULARLY AMONG OLDER WOMEN. THE SECOND PART WILL EXAMINE THE PAP SMEAR INDUSTRY, AND HOW MUCH CONFIDENCE WE SHOULD HAVE IN THE RESULTS OF THAT TEST.

BREAST CANCER STRIKES 1 OUT OF 10 WOMEN IN AMERICA TODAY. IT IS THE MOST COMMON FORM OF CANCER AMONG WOMEN, AND UNTIL 1986, IT WAS THE LEADING CAUSE OF DEATH FROM CANCER IN WOMEN. EACH YEAR, 40,000 WOMEN DIE FROM BREAST CANCER. MORE THAN HALF OF THEM ARE 65 OR OLDER. THOUSANDS MORE WILL UNDERGO EXTENSIVE SURGERY.

THE PREMATURE DEATH OF A WOMAN FROM CANCER IS ALWAYS TRAGIC. YET THE GREATEST TRAGEDY OF ALL IS THAT MANY OF THESE DEATHS COULD HAVE BEEN PREVENTED IF THE CANCER HAD BEEN DETECTED EARLIER.

WE HAVE THE TECHNOLOGY TO DETECT BREAST CANCER WHEN IT IS STILL IN ITS VERY EARLY STAGES. MAMMOGRAPHY IS A HIGHLY SAFE AND RELIABLE PROCEDURE WHICH CAN DETECT TUMORS BEFORE THEY CAN BE FELT -- WHEN THE CHANCES OF CURE ARE OVER 90%. YET VERY FEW WOMEN UNDERGO REGULAR MAMMOGRAPHY SCREENING.

LAST YEAR, APPROXIMATELY 24,000 WOMEN OVER THE AGE OF 65 DIED OF BREAST CANCER. YET IT IS ESTIMATED THAT FEWER THAN 10% OF THESE WOMEN

- more -

HAVE MAMMOGRAMS REGULARLY. ONE PRIMARY REASON FOR THIS IS THAT THE COST OF A MAMMOGRAM CAN RUN AS HIGH AS $200 -- A TREMENDOUS BURDEN FOR AN ELDERLY WOMAN ON A FIXED INCOME.

MY HOME STATE OF MARYLAND IS ONE OF ONLY 4 STATES THAT MANDATE ANY SORT OF INSURANCE COVERAGE FOR MAMMOGRAPHY SCREENING. YET THERE ARE 16 MILLION WOMEN OLDER THAN 65 IN THIS COUNTRY -- WE MUST DO MORE.

THIS IS WHY I HAVE INTRODUCED LEGISLATION TO ENABLE MEDICARE RECIPIENTS TO BENEFIT FROM THIS WELL-PROVEN SCREENING TECHNIQUE. LAST YEAR, WE ENACTED LEGISLATION MAKING A PATIENT'S EXPENDITURES FOR MAMMOGRAPHY COUNT TOWARD THEIR MEDICARE DEDUCTABLE. MY BILL PROVIDES ACTUAL MEDICARE REIMBURSEMENT FOR A MAMMOGRAM EVERY OTHER YEAR. IT ALSO HAS A BUILT IN COST-CONTAINMENT FEATURE BECAUSE IT CAPS THE REIMBURSABLE COST AT $50, AND MANDATES THAT PAYMENT BE MADE ON AN "ASSIGNMENT" BASIS. THIS PREVENTS ADDITIONAL COSTS FROM BEING PASSED ON TO THE CONSUMER.

I BELIEVE THAT NO WOMEN SHOULD HAVE TO EXPERIENCE THE DEVASTATING EFFECTS OF BREAST CANCER SIMPLY BECAUSE SHE COULD NOT AFFORD TO HAVE A ROUTINE SCREENING PROCEDURE. MY LEGISLATION IS AN IMPORTANT FIRST STEP TOWARD ENSURING THIS.

THE SECOND PART OF OUR HEARING WILL FOCUS ON PAP SMEARS. WHEN PROPERLY CONDUCTED, THIS TEST IS KNOWN TO BE RELIABLE, ACCURATE, AND ESSENTIAL FOR EARLY DETECTION OF CERVICAL CANCER. HOWEVER, RECENT REPORTS OF MISDIAGNOSES OF CERVICAL CANCER OR PRECANCEROUS CONDITIONS -- ESTIMATED TO OCCUR IN TWENTY TO FORTY PERCENT OF PAP SMEARS -- HAVE SENT A CHILLING MESSAGE TO ALL WOMEN AND THE PEOPLE WHO CARE FOR AND ABOUT THEM. THAT MESSAGE? DO NOT TRUST THE RESULTS OF THIS TEST ON WHICH SO MANY WOMEN'S LIVES DEPEND.

BARBARA ARBUCKLE, WHOSE TESTIMONY WE WILL HEAR TODAY, TRUSTED THOSE RESULTS. NOW SHE CANNOT BEAR CHILDREN. THE WOMAN YOU WILL SEE IN THE VIDEOTAPE TODAY TRUSTED THOSE RESULTS. SHE DIED.

THE WITNESS WE WILL HEAR FROM TODAY WILL TALK ABOUT SEVERAL AREAS IN WHICH THE PAP SMEAR TEST IS FAILING -- INCLUDING DOCTORS' OFFICES AND CLINICAL LABORATORIES. BUT THE GRAVEST FAILING OF ALL HAS BEEN THE FAILURE TO PROPERLY POLICE THIS INDUSTRY. WE MUST BE CERTAIN THAT THE TRAGEDIES WHICH BEFELL THE WOMEN WE ARE HEARING FROM TODAY WILL NOT OCCUR AGAIN.

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Senator MIKULSKI. Senator Adams.

OPENING STATEMENT OF SENATOR ADAMS

Senator ADAMS. I want to welcome you all to the hearing today on the subject of cancer detection in women.

No diseases strike greater fear into the hearts of women across this nation than cancer of the breast and cervix. One in ten women can expect to develop breast cancer at some time during her life. Over forty thousand women die from breast cancer each year. I applaud Senator Mikulski in her effort to expand Medicare coverage to include mammography and I am pleased to join her as a co-sponsor of this important legislation.

The record on cervical cancer is equally disturbing. Sixty thousand new cases of cervical cancer or cell abnormalities are uncovered each year. Seven thousand of those cases will result in death.

While these deaths are tragic, the real tragedy is that for the most part, they are preventable. As in the case of breast cancer, medical science has placed at our disposal the means to prevent death due to cervical cancer through early detection and treatment. Unfortunately, attempts at early detection of cervical cancer are all too often thwarted by simple human error on the part of health care providers and laboratory technicians and by a medical laboratory system which, in many cases, places a premium on quantity rather than quality.

Before we hear from the witnesses, I want to emphasize two points: First, while much of the evidence will point to medical laboratory error, it is only one part of the problem. A great deal of the problem can be traced to the doctor's offices, where inadequate samples are assembled for processing.

Many deaths also occur because women fail to have pap smear tests performed on a routine basis. This leads to my second point which is that despite the problems with pap-smear testing, it remains the best tool for prevention. This hearing would do a great disservice to the public if it in any way discouraged women from continuing to have pap smear tests performed in conjunction with their annual pelvic examinations. I cannot emphasize strongly enough the need for women to continue to adhere to the testing guidelines adopted by the American Cancer Society, the American Medical Association, the National Cancer Institute, and the American College of Obstetricians and Gynecologists.

Finally, I want to say a word of thanks to the press for its role in bringing this issue to the attention of the American public. You have been instrumental in educating women about the need to exercise constant vigilance in their effort to protect themselves against cervical cancer. Because of your efforts, women now know that they cannot assume that one test means all is well for years to come. And while I realize that the coverage has been controversial at times, it has also generated an important public debate which I am confident will ultimately spawn reforms in both the private and public sectors which will aid us in our battle against cervical cancer.

In closing, I want you to know that my concern in this matter is both professional and personal. I lost my mother to cancer, and although it was not cancer of the cervix, I know the pain and agony which accompanies a disease of this nature. As a father of two college-aged daughters, I feel compelled to speak out on this problem and to play a role in sovling it.

Senator **Mikulski**. We are going to hear witnesses today about the causes and what we can do about it. But for now, we are going to open our hearing and turn to our witnesses.

Before we proceed to the first witness, I want to ask unanimous consent to introduce into the record statements by Senators Hatch and Simon. The entirety of their opening remarks will be included at this point.

[The opening statements of Senators Hatch and Simon follow:]

STATEMENT ORRIN G. HATCH

CANCER DETECTION IN WOMEN

In 1987, it was estimated that 480,000 women in this country developed cancer and 224,000 died. Lung cancer, which is predominantly the direct result of cigarette smoking, was the leading cancer cause of death, taking the lives of approximately 45,000 women.

Breast cancer was the second most common cause of death due to cancer, resulting in approximately 41,000 lives lost -- 175 in my own state of Utah. And cancer of the cervix took the lives of approximately 6,800 of our mothers, wives, sisters and daughters. Breast cancer and cervical cancer, like lung cancer, are in large part preventable and there are some basic facts that health care experts believe every woman needs to know.

I am pleased to participate in this hearing on cancer detection in women. Specifically, we will hear today about the importance of preventive medical tests, Pap smears, mammograms and other cancer screening techniques in safeguarding the health of America's women.

Medical professionals and the experts represented by the American Cancer Society recommend that women over 20 conduct a monthly breast self-examination. If a woman finds some irregularity, she should always consult her physician. The America Cancer Society and others have also made recommendations on the use of mammography, which we will hear about today. There are other prevention efforts to reduce the incidence of cancer. For example, health professionals advise women that a diet high in fat and alcohol can influence their risk of breast cancer.

There is good news. Most lumps are not cancerous. And if a lump is cancerous, the 5-year survival rate for breast cancer which has spread is approximately 60 percent. If cancer is detected when it is still localized, the survival rate has risen to approximately 90 percent today, and if the breast cancer is not invasive, the survival rate approaches 100 percent. This data emphasis the importance of awareness and early detection.

Experts also say that women need to know about cancer of the cervix. We know that medical experts have made recommendations for regular Pap smears. The Pap test can reduce a woman's chance of dying from cancer.

There is also good news in the area of cervical cancer. The 5-year survival rate is approximately 66 percent. However, with early diagnosis, the rate increases to 80-90 percent. Again, this provides a strong case for early detection and prevention.

Early cancer detection is of vital national interest. In a recent survey, 52 percent of the American public said that prevention deserves more emphasis. Prevention experts advise women to know what constitutes a healthy lifestyle. They further urge that women know what questions to ask their health care professionals and they should to ask them.

I would add one word of caution. We live in an age of unprecedented medical advances, but medicine is not a precise science. No medical test is perfect and every test has limits. There is no way to remove the potential for human error in medical testing. And even a perfectly administered test will have some false positives and some false negatives.

I look forward to reviewing the testimony presented today. I truly agree with Benjamin Franklin's rule that an ounce of prevention is worth a pound of cure. And I look forward to working with the other members of this Committee in our ongoing efforts to increase prevention activities to reduce cancer deaths among women and all Americans.

Paul Simon

STATEMENT OF SENATOR PAUL SIMON

before the

SENATE LABOR AND HUMAN RESOURCES COMMITTEE

January 28, 1988

Mr. Chairman/Ms. Chairwoman:

I thank my distinguished colleagues from Maryland and Washington for their leadership in this area and especially for the opportunity to address the issue in this hearing. My appreciation to the witnesses who are testifying here today.

I support Senator Mikulski's legislation to provide Medicare coverage for mammograms. It is my sense that we have the opportunity to save lives and to reduce health care costs.

In 1975, approximately 24,000 women over the age of 65 died from breast cancer. It is estimated that there will be 135,000 new cases of breast cancer in 1988 and that 42,000 women will die as a result.

A recent staff paper released by the Office of Technology Assessment indicated that breast cancer is the leading cancer among women and the leading cause of cancer deaths.

Available evidence is clear that increased use of breast cancer screening would considerably reduce the severe morbidity, premature mortality and treatment costs associated with advanced breast cancer.

From the perspective of an individual 65 year old woman who is destined to get breast cancer, annual screening for ten years will reduce the chance she will die of breast cancer by 19 percent.

If all women 65 and over were screened annually, there would be a 22 percent (5,200 deaths) reduction in breast cancer deaths in the year 2000.

It is very simple. Mammography screening is necessary in order to help save lives. In order to effectively treat breast cancer, the disease must be discovered in the early stages. In the early stages., the tumor(s) are too small to be felt. The successful treatment of Mrs. Reagan's cancer is largely attributable to the early detection. Discovery of breast cancer in a localized stage with negative nodes results in an 87% five year survival rate.

If deaths from breast cancer are 30% lower in patients who have had a mamography, then why aren't all women having them routinely? Specialists tell us it is because of the cost of the test. The average cost of a mammography is $125.00, none of which is presently covered by Medicare. The cost of treating breast cancer detected in later stages is exorbitant -- estimates range from $5,000 to $42,000. And as the treatment costs go up with time, the likelihood of successful treatment goes down.

While the Office of Technology Assessment report was far from conclusive, it is my strong belief that taxpayers will benefit from investing in early detection and prevention.

I thank the distinguished chair.

Senator **Mikulski**. I would like to turn now to Jill Ireland, who heads up the National Crusade for the American Cancer Society, for her to tell her story, and then we will turn to Rose Kushner, Executive Director of the Breast Cancer Advisory Center in my own State, and a real founding mother of this movement to deal with breast cancer.

Ms. Ireland?

STATEMENT OF JILL IRELAND, HONORARY CHAIR, NATIONAL CRUSADE, AMERICAN CANCER SOCIETY

Ms. **Ireland**. Good morning, Madam Chairman, distinguished Members of the Committee, ladies and gentlemen.

How much is a woman's life worth? Can you set a dollar value on pain and suffering?

If this is the basis of holding this hearing, then the answer is obvious. According to the information provided today, it is not financially advantageous to wait until cancer is incurable before attempting to stop it.

One in ten women will develop breast cancer at some point in their lifetime. A mammography can detect cancer that is too small to be found by the most experienced examiner. Mammograms will not only save lives and personal expenses, but they will eventually save the Medicare Program a great deal of money.

The cost of treating women who discover breast cancer at an early stage can be as low as $5,000. In contrast, treatment cost for breast cancer in its later stages can total $60,000 or more. So, surely the eventual saving in treatment is more than enough to offset the cost of providing mammograms.

Now, cancer is a large group of diseases characterized by uncontrollable growth and the spread of abnormal cells. The cancer cell is a weak, confused cell. It can be killed. Its power lies in the rapidity of its growth. Early detection is vital to whether the woman harboring the disease lives or dies—and cancer is a horrible way to die.

Now, the very word "cancer" strikes terror in the hearts of all of us, but never as powerfully as when applied to oneself or one's loved ones. It is then that the real nightmare begins.

We always believe cancer is something that strikes someone else. And many people cannot even bring themselves to say the name of the disease out loud, and voices turn to whispers when delivering the news that John or Mary died of cancer.

It is almost as if saying the word will make it contagious. Cancer. I know. I have learned to speak this word aloud, while also learning to deal with the horror of this disease.

In 1984, I was told I had a malignant tumor in my right breast large enough to require a radical mastectomy. While still reeling from the shock, I was told that I would need six months of chemotherapy, and that I had better order a wig.

Well, the doctors were right. I lost my hair. It came out in handfuls one week after my first treatment—great, bird's nests of hair covered my feet in the shower, and the shoulders of my clothes. It was on the backs of chairs, on the carpets—everywhere.

Then, suddenly it was all gone, carried away by the garbage trucks and the Los Angeles sewers. My right breast had been amputated, and my life expectancy was doubtful.

The tumor had spread to my lymph nodes—too many to make me a good statistic for survival. Well, aggressively, my oncologist threw the book at me—adriamycin, cytoxin, F-5-U. These lifesaving drugs extended my life while making me weak with nausea.

The miasma of sickness got worse as the months went by. Toxic drugs accumulated in my system. At times I was so ill, and my grip on life so tenuous, I believed that if I closed my eyes and stopped concentrating, I would die.

I never stopped fearing the treatments. Each time I showed up at my oncologist's office, it took all the will power and courage at my command to hold out my arm, don the heavy, odorous ice helmet, and allow the nurse to slide the needle into my burned-out veins.

As I speak these words and the memories return, I still feel the sickness in my gut. But I am grateful for the benefit of this harsh treatment.

Although I am still not in remission, I am alive, and I have enjoyed three good years, and I am optimistic that there will be many more.

But if it were not for a mammogram, I would not be standing before you today, pleading for the lives of thousands of American women. My tumor was not detectable by examination. It took a mammogram to save my life.

If you pass this bill, so many older women can be spared radical surgery and painful treatments. You know, when you are sitting, vulnerable, on a cold metal table in a small paper gown, cancer is a great leveller. It knows no boundaries. It does not respect income levels, ethnic distinctions, or social standing. It strikes the young—people in the full stride of their most productive years—and it strikes the elderly—those depending on a mere $400 from Social Security.

The elderly must have access to high-quality mammography whereby tumors can be detected in their earliest stages. It is equally necessary that the cost be covered by Medicare.

You know, it is difficult in many cases to even get women to go to a doctor when they discover a lump. The thought of a mammogram is already an emotional move, hard to persuade women to take, especially older women. Add to this the final burden, ranging from $50 to $200 every year, and it is easy to understand why an elderly woman on a small, fixed income does not go for an annual mammogram. When she is faced with a decision to spend so much of her meager income to put food on the table or to buy a mammogram, the choice becomes obvious.

What is desperately needed now is an expansion of the Medicare Program to cover the expense of annual mammograms for the elderly. The lives and financial solvency of many women depends upon rapid Congressional action. And it seems to me a social crime when it is now possible for doctors to detect breast tumors at a very early stage with the use of screening, that women who lack funds are being denied the chance to be spared.

A mastectomy cuts at the very core of a woman—our breasts, which have nurtured and pillowed every man and woman here today.

One year ago, I had a lumpectomy in my left breast. It was a small, one-day procedure, leaving only a small, invisible scar. That, compared to the brutal slash of the surgeon's knife on my right side only serves to urge me to speak out today for your mothers, sisters, daughters, and wives.

Everyone gets older, and few can predict the circumstances in which our daughters may find themselves in later years. But if we care, we can make sure that none of our loved ones will die piece by piece, in pain, hooked up to machinery, aching from numerous surgeries and the devastating disappointments of recurring, spreading cancer, just for the want of a mammography.

I have been honored to testify before you, and I thank you, Senator Mikulski, and all of you on the Committee, for conducting this hearing and for your commitment to health care. Millions of women await your decision.

Thank you.

[The prepared statement of Ms. Ireland follows:]

AMERICAN
CANCER
SOCIETY

TESTIMONY OF

JILL IRELAND

LOS ANGELES, CALIFORNIA

REPRESENTING THE
AMERICAN CANCER SOCIETY

"CANCER DETECTION IN WOMEN"

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

JANUARY 28, 1988

For more information please contact:
Kerrie B. Wilson
American Cancer Society
(202) 546-4011

Good morning, Mr. Chairman, distinguished members of the Committee, ladies and gentlemen. I am pleased to be here today, as a representative of the American Cancer Society, and as an individual who has firsthand experience with the issues at hand.

How much is a life worth?
Can you set a dollar value on pain and suffering?

Legislation has been introduced by Senator Barbara Mikulski to provide insurance coverage for screening mammography to women who are enrolled in our federal health care program -- Medicare. While it is not the charge of this committee to decide the fate of this legislation today, each of you has a very important vote to cast down the road. Medical science has made it possible, through an x-ray of the breast called a mammograph, to prevent much of the suffering and loss associated with breast cancer. It is no longer acceptable to wait until cancer is incurable before we attempt to stop it.

The American Cancer Society says that one in ten women will develop breast cancer at some point in their lifetime. There will be an estimated 135,000 new cases of breast cancer in women in 1988, and 42,000 women will die from the disease this year. Many scientific studies have demonstrated that routine mammography screening will detect tumors in the breast that are too small to be found by the most experienced examiner.

Cancer is a large group of diseases characterized by uncontrollable growth and the spread of abnormal cells. However, the cancer cell is a weak, confused cell. It can be killed. Its terrible power lies in the rapidity of its growth. Early detection is vital in determining whether the woman harboring cancer will survive. And cancer is a horrible way to die.

The very word _cancer_ strikes terror in the hearts of all of us, but never as powerfully as when applied to one's self or one's loved ones. It is then that the real nightmare begins. We always believe cancer is something that strikes someone else. Ironically, many people can't even bring themselves to say the name of this disease out loud. We hear voices turn to whispers when delivering the news that Mary or John died of _cancer_, almost as if _saying_ the word will make it contagious.

Cancer. I know. I have learned to speak this word aloud, while also learning to deal with the horror of having the disease. In 1984 I was told I had a malignant tumor in my right breast. The tumor was so large that my physician told me I would need to have a radical mastectomy -- removal of the breast and the lymph nodes under my arm. While I was still reeling from the shock of this surgery and the loss of my breast, I was told that because the cancer had gone so far I would have to undergo six months of chemotherapy, and that I had better order a wig.

Well, the doctors were right. I lost my hair. It came out in handfuls one week after my first treatment. Great bird's nests of hair covered my feet in the shower and the shoulders of my clothes. It was on the backs of chairs, on the carpet, everywhere. Then suddenly it was all gone, carried away by the garbage truck and the Los Angeles sewers.

My breast had been amputated and my life expectancy was doubtful. The tumor had spread to many lymph nodes, too many to make me a good statistic for survival.

Agressively, my oncologist threw the book at me -- adriamycin, cytoxin and F-5-U. These life-saving drugs extended my life while making me weak with nausea.

The sickness got worse as the months went by. Toxic drugs accumulated in my system. At times I was so ill and my grip on life so tenuous, I believed that if I closed my eyes and stopped concentrating, I would die.

I never stopped fearing the treatments. Each time I showed up at my oncologist's office, it took all the will power and courage at my command to hold out my arm, don the heavy, odorous ice helmet and allow the nurse to slide the needle into my burned-out veins.

As I speak these words and the memories return, I still feel the sickness in my gut. But I am grateful for the benefit of this harsh treatment.

Although I am still not in remission, I am alive. I have been luckier than many women -- I have had the support of my husband, Charles, my seven children, and my friends. I have enjoyed three good years. And, I am optimistic that there will be many more.

If it were not for a mammogram, which detected my cancer before I did, I would not be standing before you today, pleading for the lives of thousands of American women. My tumor was not detectable by examination. It took a mammogram to save my life. If all women knew about the benefits of screening, and if it were available to them, so many women could be spared surgery, painful treatment, and death.

Breast cancer is a great leveler. It knows no boundaries. It does not respect income levels, ethnic distinctions or social standing. It strikes the young, people in the full stride of their most productive years and it strikes the elderly -- many of whom are surviving on a mere four-hundred dollars a month from Social Security.

All women must have access to high-quality mammography so that tumors can be detected before they kill. You have the opportunity to provide this benefit to the elderly, through our Medicare program. Some private insurers are beginning to include coverage for routine screening procedures in their policies, but too many of our elderly do not have private insurance, and could not afford this option even if they did.

It is very difficult in many cases to get women to go to a doctor when they discover a lump in their breast; it is also difficult to convince them to have a routine mammogram which might detect a tumor they can't feel. Add to this the financial burden ranging from $50 to $200 every year, and it is easy to understand why an elderly widow on a small, fixed income does not go for an annual mammogram. When faced with the decision to spend so much of her meager income to put food on the table or to buy a mammogram, the choice becomes obvious.

What is desperately needed now, Mr. Chairman, is an expansion of our federal health care program to cover the expense of annual mammograms for the elderly. The lives and financial solvency of many women depends upon rapid Congressional action. It seems to me a social crime, when it is now possible for physicians to detect breast tumors at a very early stage with the use of screening, that women who lack funds are being denied the chance to be spared from suffering.

A mastectomy cuts at the very core of women, our breasts, which have nurtured and pillowed every man and woman here today.

A year ago my doctors discovered a tumor in my left breast. Fortunately, they caught it early and were able to save my breast, performing a lumpectomy to remove the tumor. It was a relatively easy, one-day procedure, leaving only a small invisible scar. That compared to the brutal slash of the surgeon's knife on my right side only serves to urge me to speak out today for your mothers, sisters, daughters, and wives.

Everyone gets older and few can predict the circumstances in which our daughters may find themselves in later years. But if we care, we can make sure that none of our loved ones will die piece by piece in pain, hooked up to machinery, aching from numerous surgeries and the devastating disappointment of a recurring, spreading cancer.

This cancer victim begs you to spare millions of women from the enemy within for want of a mammogram.

I have been honored to testify before you and I thank you for conducting this hearing, and for your commitment to the public health. Millions of Americans await your decision. Thank you.

Senator MIKULSKI. Thank you, Ms. Ireland, for that moving testimony, and I am sure we will learn more as we talk with you and also reading your book, "Life Wish".

Now we would like to hear from Rose Kushner, founder and Executive Director of the Breast Cancer Advisory Center, co-founder of the National Alliance of Breast Cancer Organizations, and a former member of the National Cancer Advisory Board—someone who has certainly taken her personal situation and made it public and made it political in the best sense of that word.

It is an honor to welcome you, Ms. Kushner.

STATEMENT OF ROSE KUSHNER, FOUNDER AND EXECUTIVE DIRECTOR, BREAST CANCER ADVISORY CENTER, COFOUNDER OF THE NATIONAL ALLIANCE CANCER ADVISORY BOARD

Ms. KUSHNER. Thank you, Senator Mikulski and distinguished Members of the Committee. My name is Rose Kushner. In 1974, I was treated for breast cancer, and I was lucky enough to have had it diagnosed early enough that I did not have to endure any chemotherapy and go through the experiences that Jill Ireland just described so eloquently.

I wrote a book about the disease, "Alternatives: New developments in the war on breast cancer" and began the Breast Cancer Advisory Center to give women and men (men do get breast cancer; one of every hundred is male) information and referrals about diagnosis and treatment.

As you said, in 1980, I was appointed to a six-year term as a member of the National Cancer Advisory Board (NCAB) by President Jimmy Carter. I served until May 1986.

In 1985, helped start the National Alliance of Breast Cancer Organizations (NABCO), which now includes 92 member organizations from all over the country—all made up of women, and again, men, concerned about every aspect of breast cancer.

I am here today to represent NABCO and all women, to urge passage of the bill you introduced last May, S. 1161. This bill will require Medicare to cover the costs of screening by mammography.

I would like to remind everyone, as you did, that this is the X-ray examination that found a 7-millimeter tumor in Mrs. Reagan's left breast when it was still too small to be felt, even by top breast cancer experts.

Mrs. Reagan is lucky that the tumor was diagnosed and treated at this very early stage of growth, because she has virtually a 100 percent guarantee that she is cured without any chemotherapy or radiation. But Mrs. Reagan is also lucky that she could afford mammography screening as part of her routine physical examination.

As you and Ms. Ireland have both said, most women older than 65, unlike Mrs. Reagan, live on their Social Security incomes and cannot afford to have this life-saving test.

According to the National Cancer Institute and the American Cancer Society, 130,000 new cases of breast cancer were diagnosed in 1987, and I understand 142,000 are projected for 1988. Almost half of these patients will be older than 65. I find it bizarre and ironic that the Medicare Program—the program the Federal Government created to improve the health and prolong the lives of our country's senior citizens—does not cover the cost of mammography to detect this potentially fatal disease when it is early and more likely to be cured. Yet the National Cancer Institute, another part of the same Federal Government, recommends, and has been recommending since 1977, that every woman older than 50 be screened by mammography annually.

Before continuing, I would like to point out that there is a difference between screening and diagnostic mammography. Diagnosis is covered by Medicare. Diagnostic mammography is done when a woman has already found a lump, a thickening or another symptom. It, the cancer, is already too advanced to be "caught very early," if it can already be palpated (felt).

"Screening" means women who have absolutely no symptoms—or men—are X-rayed to see if there is something hiding in their breasts, long before it can be felt. This is the examination that Mrs. Reagan had, a screening mammography, as part of her routine physical at the Bethesda Naval Hospital.

It has been known for more than ten years that diagnosing and treating a breast cancer when it is too small to be felt can cut the mortality rate, the death rate, of women older than 50 by about 30 percent. Thirty percent may not sound large, but it translates, according to current statistics, into more than 25,000 lives of senior citizens over 65.

Dr. Philip Strax, who is here to testify today, was the director of the initial study by the Health Insurance Plan (HIP) of New York that began in the early 1960s. These HIP data have been since verified by recent data from Sweden and from Holland. All of the studies show a reduced mortality rate in women older than 50, and Dr. Strax has testified about them before other committees of the Congress.

Now, if these lifesaving benefits of mammography have already been proven in three countries, why are about 50 percent of new patients in the United States diagnosed after the cancer has already spread to the axillary lymph nodes, the glands in the armpit?

This question has been answered by several polls. Primary care physicians—family doctors and gynecologists, the doctors women go to first—are reluctant to order mammography because it is so expensive. Why is it so expensive? Radiologists, the specialists who take the mammograms and interpret them, say they cannot afford to lower the prices because the equipment, the salaries of their personnel, their rent, their light bills and so on, are the same if they take one mammogram a day or if they take 50.

So women are caught in the proverbial vicious circle. They are not being referred for mammography, because their doctors say it is too expensive, but the reason the examination is so expensive is that too few women are being mammographed. But this is a vicious circle that has a natural, logical break. If even only 25 percent of the 16 million women over 65 are screened, the increased volume would dramatically reduce the cost per patient.

Dr. Strax will testify that his high-volume clinic in Fort Lauderdale, Florida, does quality screening at a maximum charge of $35.

"Cost containment" is the reason why Medicare is not covering breast screening, even though this is penny-wise and pound-foolish. As Ms. Ireland has already said, and as the Committee will hear later, it costs many more taxpayers' dollars to treat advanced breast cancer than it does to detect the disease by mammography screening before it has spread.

No dollar value, of course, can be put on the pain, suffering and premature death that inevitably follow a diagnosis of advanced breast cancer. However, a dollar value can, and has been, put on the cost of screening versus the cost of late detection and death. Dr. Dixie Melillo will testify about these costs later in this hearing.

The first pioneering legislation to help women afford annual mammography was enacted by our home State of Maryland in 1986, effective July 1st of that year. Since then, it has also been enacted in Texas, Massachusetts and California. I am glad that Maryland, Texas, Massachusetts and California have such laws, but it is not enough to have protection in only four of 50 States, when there are more than 16 million women older than 65 living in the other 46 States. Only a Federal law can provide the health care American women have a right to expect.

Senator Mikulski, you have said that I have turned breast cancer into a political issue. It is indeed a very political issue. Every penny that is spent on breast cancer research is appropriated by Congress. All the money that goes to the National Cancer Institute is appropriated by Congress. And I cannot think of anything that makes breast cancer more political than appropriations of money by Congress.

We women compose more than half of the population in this country, and we have a right to expect that our representatives in this historic Hundredth Congress will do whatever is necessary to help us. Right now, Medicare coverage of screening by mammography is an excellent first step.

I thank you for inviting me and allowing me to testify before the Committee.

Thank you.

[The prepared statement of Ms. Kushner with attachments, follows:]

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Consultant National Cancer Institute
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TESTIMONY OF ROSE KUSHNER

FOUNDER AND EXECUTIVE DIRECTOR
BREAST CANCER ADVISORY CENTER
CO-FOUNDER: NATIONAL ALLIANCE OF BREAST CANCER ORGANIZATIONS
FORMER MEMBER: NATIONAL CANCER ADVISORY BOARD

BEFORE

THE LABOR AND HUMAN RESOURCES COMMITTEE OF THE U.S. SENATE

JANUARY 28, 1988

Senator Mikulski, Distinguished Members of the Committee, Ladies and Gentlemen:

My name is Rose Kushner. In 1974, I was treated for breast cancer and wrote a book about the disease, Alternatives: New developments in the war on breast cancer. I began and became director of the Women's Breast Cancer Advisory Center in 1975 to give women (and men) information and referrals about diagnosis and treatment. In 1980, I was appointed to a six-year term to the National Cancer Advisory Board (NCAB) by President Jimmy Carter and served until May, 1986. I also helped found the National Alliance of Breast Cancer Organizations (NABCO), a national "umbrella" covering 78 organizations throughout the country.

By virtue of their groups' membership in NABCO, more than 250,000 Americans concerned about national issues related to all aspects of breast cancer are now unified and represented in Washington. I am currently serving as the director of NABCO's Washington, D.C. office and am writing to give our support to S.1161, introduced by Senator Barbara Mikulski in May, 1987.

(more)

P.O. Box 224   Kensington, Maryland 20895

This bill, when passed and signed into law, will require Medicare to cover the costs of mammography -- the X-ray examination that revealed he presence of a tumor in Mrs. Nancy Reagan's left breast when the mass was still too small to be felt, even by top breast-cancer experts. Mrs. Reagan is lucky that the tumor was diagnosed and treated at this stage of its growth, because such early detection means she has virtually a 100% guarantee that she is cured.

Mrs. Reagan is also lucky that she could afford to have mammography as a routine part of her physical examination. Most women older than 65 must live on their Social Security incomes and cannot afford to have this lifesaving test.

According to the National Cancer Institute (NCI) and the American Cancer Society (ACS), 130,000 new cases of breast cancer were diagnosed in 1987, and statistics from previous years show that almost half of these new patients will be older than 65. It is imperative that the Medicare Program -- created by the Federal Government to improve the health and prolong the lives of our country's senior citizens -- cover the cost of mammography to detect this potentially fatal disease when it is early and more likely to be cured.

For more than a decade, scientists have known that diagnosing and treating a breast malignancy when it is preclinical (microscopic) and non-palpable (too small to be felt) will save the lives of thousands of our senior female citizens. A randomized screening program conducted by the Health Insurance Plan of New York in the 1960s (and directed by Dr. Philip Strax who is here today to testify before this Committee) proved that the 10-year death rates of the women older than 50, who were diagnosed to have breast cancer after being examined by mammography and a clinical examination, were more than 30% lower than those of women who were examined but not mammographed. Dr. Strax presented these data in hearings held by the House Select Committee on Aging (June 28, 1984 and October 23, 1985). On November 3, 1987, these lifesaving benefits of mammography were described by Dr. Myron Moscowitz -- director of a screening center in Cincinnati.

(more)

This was a hearing before the House Subcommittee on Health of the Ways & Means Committee, held in support of H.R. 2935, introduced by Congresswoman Mary Rose Oakar, and of H.R. 3573, introduced by Congressman Fortney "Pete" Stark.

If these lifesaving benefits of mammography have already been proven, why are about 50% of new patients diagnosed after the cancer has already spread?

This question was answered by several polls conducted by the American Cancer Society and the American College of Radiology: Most doctors are reluctant to order mammography because of its cost (as high as $200), while radiologists -- the specialists who interpret mammograms -- argue that dedicated equipment, the salaries of trained and certified technologists, supplies and overhead are the same, whether they do one mammography examination each day or 50. It is a proverbial vicious circle: They are not being referred for mammography because of its high cost; the reason the examination is so expensive is that too few women are being mammographed!

But this is one vicious circle that has a natural logical break. If even only 25% of the 16 million women over 65 were screened, the increased volume would dramatically reduce the cost-per-patient. Dr. Strax has testified that his high-volume clinic does quality screening at a maximum charge of $35.00.

Women are also being faced by another confusing paradox: The NCI -- the federal government's own agency leading the National Cancer Program -- has been recommending that all women older than 50 be screened every year, while another federal health program -- Medicare -- does not pay for this lifesaving early detection examination!

"Cost containment" is the reason why Medicare does not cover breast screening, even though this is a penny-wise and pound-foolish policy: It costs many more taxpayers' dollars to treat advanced breast cancer than it does to detect the disease by mammography screening before it has spread.

(more)

Of course, no dollar value can be put on the pain, suffering and premature death that inevitably follow a diagnosis of advanced breast cancer.

Savings will not be seen immediately, of course, because more women will be diagnosed with advanced disease and will need more expensive treatments, longer hospital stays, etc. A very recent report from the Congress' Office of Technology Assessment has also pointed out that such a new screening program will probably increase Medicare costs because of "false positive" diagnoses. Early expenses, however, will drop as the screened women are diagnosed with early breast cancer that requires far less treatment -- therefore, far lower bills.

The first legislation to help women afford annual mammography was enacted by my home state of Maryland in 1986. Since then, even more comprehensive mammography legislation was enacted in Texas: Massachusetts and California have also enacted laws for more extensive insurance coverage -- all the result of assistance given by NABCO, the National Alliance of Breast Cancer Organizations.

I am glad that Maryland, Texas, Massachusetts and California have such pioneering legislation, but it is not enough to have this protection only for women in 4 of 50 states, when there are more than 16 million women older than 65 in the United States. Only a Federal law can provide the health care American women have a right to expect.

Breast cancer has become a political issue in the United States. Women compose more than half of the U.S. population, and we have a right to expect our representatives in the historic 100th Congress to do whatever they can to help us. Medicare coverage of annual screening by mammography is an excellent first step.

Respectfully submitted,

Rose Kushner, Executive Director
Breast Cancer Advisory Center
Co-founder: National Alliance of
Breast Cancer Organizations
Former member: National Cancer
Advisory Board

Enclosures

USA TODAY - October 19, 1987

COVER STORY

Her checkups helped Nancy beat cancer

Breast cancer: 1 in 10 USA women will get it; 41,300 will die this year

By Mark Mayfield
and Johanna Neuman
USA TODAY

BETHESDA, Md. — Flowers and telegrams poured in Sunday to Nancy Reagan's hospital suite — ranging from a "get-well" message from an 11-year-old boy to bouquets from Saudi Arabia's King Fahd and Britain's Margaret Thatcher.

But the first lady's doctors delivered the most encouraging news: Final tests following her breast cancer surgery Saturday show no spread of the disease beyond her left breast, which was removed.

Mrs. Reagan, 66, underwent a "modified radical mastectomy" — a traumatic surgical procedure. Yet her prognosis "for full recovery is excellent," said Dr. John Hutton, the White House physician.

The news sends a message to women everywhere.

The first lady's case appears to be a classic example of the benefits of early detection, say experts. A quarter-inch lump in her breast was discovered Oct. 5 in a routine mammogram, a low-dose X-ray recommended annually for women over 50.

Five-year survival rates for breast cancer detected as early as Mrs. Reagan's are 90-100 percent, the American Cancer Society says. But a survey found just 43 percent of women over 40 have had a mammogram; only 29 percent

Please see COVER STORY next page ▶

Continued from 1A

have had one in the past two years.

Physicians who for years have encouraged check-ups and mammograms expect to see more women coming in for screening due to the publicity surrounding Mrs. Reagan's illness.

"Nancy Reagan's case shows that mammography can detect cancer when it's fully curable," says Dr. William Feller, a breast cancer expert at Georgetown University in Washington, D.C.

Says Dr. Wende Logan, a radiologist and director of the Breast Clinic of Rochester, N.Y.: "When something like this happens, women go to their physicians and request a mammogram. This is what happened with Betty Ford and Happy Rockefeller."

Both former first lady Ford and Happy Rockefeller, widow of the late vice president Nelson Rockefeller, have had mastectomies. They were among those placing phone calls to Bethesda Naval Hospital Sunday to wish Mrs. Reagan well.

Among hundreds sending telegrams: actress Ann Jillian, who underwent a double mastectomy in 1985.

"Mrs. Reagan's strength will take her through this and no doubt will help alleviate the fear of other women," said Jillian, in Toronto filming *The Ann Jillian Story* — a movie about her ordeal. "There are thousands of women ... around the nation who are proof that thanks to early detection, life can go on after breast cancer, and in a very happy, fulfilling way."

Mrs. Reagan is "recovering remarkably well from surgery," Hutton said. She ate her usual breakfast Sunday: juice, papaya, bran cereal with skim milk and decaffeinated coffee. Wearing a pink quilted robe, she walked the hospital halls on the arm of the president, who brought a gift: a mirror wrapped in white paper with a red-white-and-blue ribbon.

The couple read get-well cards and joined in a call to the parents of Jessica McClure, the toddler rescued from an abandoned well in Texas.

Mrs. Reagan is staying in the hospital's presidential suite, painted pale green with a TV set at the foot of the bed and a desk nearby.

An adjoining conference room is flooded with flowers and gifts — from world leaders and ordinary citizens.

Mrs. Reagan's press secretary, Elaine Crispen, said she knows of no plans for the Reagan children to visit the hospital, but that the first lady's personal assistant has been in touch with them by phone.

She was expected to be in the hospital until week's end, but may be ready to go home earlier. Meanwhile, doctors are prescribing Tylenol and use of her left arm, where lymph nodes were removed. "They told her not to pamper it," said Crispen, "to use it so it doesn't get weak." Crispen said Mrs. Reagan is planning to attend a Nov. 10 state dinner honoring Israeli Prime Minister Yitzhak Shamir.

Mrs. Reagan's new status as a medical role model clashes with her passion for privacy, especially on health matters.

She was so upset with detailed press coverage of her husband's colon cancer surgery in 1985 that all medical news since has come from White House spokesmen rather than doctors.

But following the example of Ford and Rockefeller, Mrs. Reagan has spoken out about her experience: "It certainly shows the value of regular check-ups," she was quoted as saying after surgery.

She even joked Sunday that she and the president had decided to exchange Christmas gifts of "framed copies of our medical diagrams" that have been appearing in the news.

But aides and friends predict she won't make a crusade of her cancer.

"If she can set a good example of women having early and regular check-ups, I'm sure she will," said Crispen. "But I doubt she'll do whole speeches on it. She's busy enough with the drug program and the foster grandparent program."

Says long-time friend Caroline Deaver, whose husband Michael was a top White House aide: "I'm sure she'll handle this with the same kind of strength and straightforwardness she's handled everything. She'll find the balance between what is common knowledge and what she feels comfortable with."

The first lady's example is important, doctors say, because incidence of breast cancer is at an all-time high as the percentage of older women in the population increases. One in 10 USA women will develop it. This year alone, 41,300 will die of it.

While the first lady is an example of what regular check-ups can do, there is controversy over her treatment choice.

Some surgeons criticized Mrs. Reagan's decision to immediately undergo removal of her breast and under-arm lymph nodes without taking time to weigh other less drastic options, such as lumpectomy (removal of the tumor and adjoining tissue, but not the entire breast), followed by radiation treatment.

But White House officials said Mrs. Reagan was given options and chose a modified radical mastectomy, like many older patients who don't want to undergo lengthy radiation treatment.

"There may be a little disagreement among experts about whether Mrs. Reagan's treatment was more extreme than it needed to be," said Georgetown's Dr. Feller.

"But we certainly know that she had outstanding surgeons," Feller said. "And from every indication, the options were explained to her and she participated in the decision-making process. That's the important thing."

Contributing: Arlene Vigoda, Kim Painter, Jessica Lee

The Lessons From Mrs. Reagan's Case

Early detection through mammography greatly reduces the risks of breast cancer

© SIU—PETER ARNOLD

In spite of Nancy Reagan's misfortune, her case presents two vital and encouraging messages to every woman about breast cancer. First, the low-dose X-ray technique called mammography is the best method for catching breast cancer early, when it is most likely to be curable. "Mammography is the gold standard of early cancer detection," says Dr. William F. Feller of Washington's Georgetown University Medical Center. "If we could get them early, we could cure 90 percent."

And the second lesson: the day of the most disfiguring, radical surgery for breast cancer is long gone, replaced by simpler and equally effective alternatives. "Advances [in treatment] in the last 10 years have made a tremendous improvement in quality of life," says Dr. George Canellos of Boston's Dana-Farber Cancer Institute.

To be sure, breast cancer remains a common and deadly disease. This year 130,000 American women will be diagnosed—and 41,000 will die. Still, about a million U.S. women who have had the disease are still alive, and the survival rates are improving. In the 1940s, 78 percent of women with early-stage breast cancers survived for at least five years after diagnosis; today 90 percent do.

Many factors: Breast cancer tends to strike older women. More than three-quarters of its victims are over 50, only 8 percent under 40. There is no single risk factor, as there is with smoking and lung cancer; there are many. Women whose mothers or sisters have had the disease are more susceptible. A woman who has cancer in one breast has a better-than-average chance of getting it in the other. Fats in the diet and obesity have been linked to breast cancer by some, but others dispute the theory.

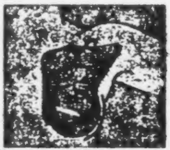
To detect breast cancer, physicians advise women to perform monthly self-examinations and to have routine physicals twice a year. But mammography is the most effective safeguard, because it can find tumors too small to be felt. That apparently was the case with Nancy Reagan. "Early detection is finding smaller lumps and that translates into a higher cure rate," Canellos says.

Indeed, studies show that deaths from breast cancer are up to 30 percent lower among women who have had mammography than among those who haven't been screened. One large survey by the American Cancer Society and the National Cancer Institute involving 280,000 women showed that regular mammograms improved breast-cancer survival among women over 50; 81 percent were still alive eight years after diagnosis, compared with the national survival rate of 65 percent.

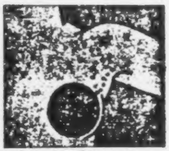
Another screening technique called thermography detects breast tumors by the amount of heat they give off. The thermogram picks up infrared radiation from the breast and suspicious "hot spots" turn up in color. Thermography doesn't work well, however, in women with especially fat breasts. And most cancer specialists believe that it is only an adjunct to mammography and not to be trusted by itself.

Mammography, too, has its limitations. It picks up fluid-filled cysts and other "benign" growths. And it can miss up to 10 percent of malignant tumors. Moreover, the mammography of a decade ago delivered a dose of radiation that some experts suspected might actually increase the risk of cancer. This problem has been corrected by newer equipment that provides much lower exposure to X-rays, as well as guidelines to reserve mammography for specific groups of women. The ACS advises all women between 35 and 39 to have a "base line" mammogram. Then they should have one every other year until 50, at which time an annual X-ray

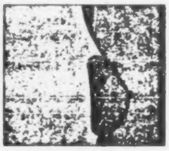
Mastectomies: Five Options



Radical
Removal of the breast, lymph nodes and muscles on the chest wall. Considered the standard surgery only 10 years ago, it is now rarely performed.



Modified radical
Nancy Reagan opted for this approach. She underwent removal of the breast and lymph nodes. This procedure is now the most common for early-stage breast cancer.



Total
Removal of breast alone. Sometimes a few lymph nodes close to the breast are also taken to check for spread of the cancer.

SOURCE: AMERICAN CANCER SOCIETY

© HOWARD SOCHUREK—STOCK SHOP

Two testing procedures: *Mammography (left) offers best chance of catching cancer, 'hot spot' on thermogram of breast could be a tumor*

would be in order. Some experts advise that women over 35 with family histories of breast cancer should probably have mammograms every year, as well. Unfortunately, some women avoid the exams because they can be somewhat painful; the breasts are pressed against the X-ray machine in order to decrease the amount of radiation needed to pass through the tissue.

If a mammogram shows a lump, the surgeon may insert a needle into the breast to withdraw fluid to detect malignant cells under the microscope. If there is not fluid to draw, the lump may be removed through a small incision, often with a local anesthetic. If the tumor is malignant, doctors nowadays consult with the woman before proceeding to major surgery.

As recently as a decade ago, the traditional operation was the Halsted radical mastectomy, named for the famous turn-of-the-century Johns Hopkins University surgeon who devised it. The surgeon removes the breast along with all of the lymph nodes under the arm (the route by which cancer may spread to other parts of the body), as well as the muscles of the chest beneath the breast. Beside this disfigurement, the patient can develop a grotesquely swollen and painful arm because lymph fluid no longer drains normally. Surgeons now acknowledge that such a drastic procedure is seldom needed.

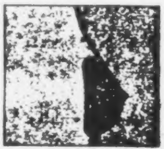
Breast rebuilding: About three-quarters of breast-cancer patients today undergo the same kind of "modified radical" as Nancy Reagan. The surgeon removes the breast and the lymph nodes under the arm. Often, plastic surgeons take part in the procedure and begin rebuilding the breast area immediately after the cancer surgeons have finished. Less commonly, surgeons remove only the breast, along with a few lymph nodes to check for spreading cancer. In another, rare, operation, the surgeon simply removes the breast tissue, leaving skin and nipple intact. The empty space can then be filled with a plastic insert. Some doctors used to advise this procedure as a preventive measure for women with pathological breast changes that could become cancerous. Most now disapprove of it.

In order to preserve the breast, many women now have a lumpectomy, in which only the tumor itself with some normal tissue margin is removed. Often some lymph nodes are also taken for testing. Following surgery, the patient gets a six-week course of radiation therapy directed at the breast and possibly lymph nodes adjacent to the breast. According to two studies, women do just as well after lumpectomies as they do with mastectomies. Lumpectomies, however, aren't advised for women with small breasts or if the tumor involves the nipple area, because the result is not cosmetically desirable. Doctors also don't recommend this procedure if the tumor is larger than two inches or so in diameter because the cancer is more apt to have spread. And the radiation that always accompanies lumpectomy can "sunburn" the breast and cause pain and tenderness.

Following surgery, tumor cells are tested to see if they contain hormone "receptors." The presence of receptors means that the growth of the tumor was actually being stimulated by the female hormones estrogen and progesterone. So patients who test positive for receptors are given tamoxifen, a drug that counters the activity of these female hormones. Women who have not reached menopause often get other potent anticancer drugs if any of the lymph nodes under the arm contain cancer cells. That's because breast cancer tends to be more "aggressive" and apt to recur in premenopausal women. Drugs, however, cause severe toxic reactions in many women, including nausea and vomiting, as well as fatigue and loss of hair. But the benefits of chemotherapy outweigh the side effects, in the view of many experts.

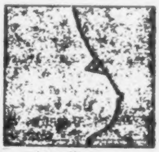
Even with an arsenal full of drugs and more sophisticated ways to use the surgeon's scalpel and the physician's X-rays, the key to curing cancer of the breast remains the same as it was in the days of Halsted. Early detection.

MATT CLARK *with* MARY HAGER *in Washington and* LISA DREW *in New York*



Subcutaneous

Removal of breast tissue but not the nipple and skin. This procedure, not usually performed now, was once thought to help treat "precancerous" changes in the breast.



Lumpectomy

Removal of tumor and a sampling of lymph nodes, followed by radiation treatments; often considered a viable alternative to a modified radical procedure.

BLUMRICH—NEWSWEEK

Risk Factors

One in 10 American women develops breast cancer. Certain traits indicate levels of risk.

Higher Risk

Older than 50
Cancer in other breast
Family history of breast cancer
No pregnancies
Firstborn child after 30
Menstruation onset before 12
Menopause after 50
Obesity
High-fat diet

Lower Risk

Younger than 50
No family history of breast cancer
Both ovaries removed early in life
Full-term pregnancy before 30
Menstruation onset after 12
Early menopause
Slenderness
Low-fat diet

SOURCE: AMERICAN CANCER SOCIETY

THE NEW YORK TIMES, SATURDAY, OCTOBER 17, 1987

Mammograms: Safer and More Accurate

By GINA KOLATA

Mammography, the diagnostic technique that detected a possibly cancerous lesion in Nancy Reagan's left breast, has evolved to the point that doctors using it can not only find tumors but can also tell with increasing accuracy whether they are malignant.

Radiologists caution that doctors must still confirm the diagnosis by removing cells from the tumor and examining them under a microscope.

Preliminary diagnoses turn out to be correct in 75 to 80 percent of cases, said Dr. Robert Goodman, chairman of the department of radiation therapy at the University of Pennsylvania Medical School.

When it appears likely that a tumor is cancerous, patients may discuss treatment options even before a biopsy confirms the diagnosis. Mrs. Reagan has apparently decided to have her left breast removed, if needed, rather than limiting surgery to the lump and undergoing radiation treatments.

Advances Since 1960's

Mammography is an X-ray of the breast that uses very small doses of radiation. Because most tumors are more dense than surrounding breast tissue, they show up as shadows.

"Mammography first became a serious diagnostic tool in the 1960's," said Dr. Kent Osborne, a professor of medicine at the University of Texas Health Science Center in San Antonio. A large study in in the 1960's by the Health Insurance Plan of New York showed that routine mammography could save lives by detecting breast cancer early, when it is most curable.

But Dr. Osborne said "mammography got a bad name" because the X-ray machines of the 1960's sometimes administered what some critics thought were dangerously high doses of X-rays.

> Preliminary diagnoses of cancer are correct 75% of the time.

Over the past 20 years and especially in the 1970's, the machines were improved. Today, properly used, they give only minimal doses of radiation and provide clearer pictures of tumors, Dr. Osborne said. Studies have shown that mammography can detect many tumors before they can be felt and that routine mammography can reduce the death rate from breast cancer by 30 percent.

The American Cancer Society and the American College of Radiologists now recommend that all women have a mammogram sometime between the ages of 35 and 40 for comparison with later X-rays. The experts suggest that women have mammograms every few years from the ages of 40 to 50, and every year after 50. Yet not even 10 percent of postmenopausal American women have regular mammograms, Dr. Goodman said.

20% Undetected by X-rays

But mammograms do not detect every tumor, experts say. As many as 20 percent of tumors that can be felt do not show up at all on mammograms because, in some women, breast tissue is roughly as dense as tumor tissue, radiologists said.

Fewer than 50 percent of all abnormalities detected by mammograms are malignant, experts said. But those that are malignant tend to have a distinctive appearance.

The malignant tumors, according to Dr. Goodman, "do not have perfectly round borders. They have a star-shaped appearance, with sort of tentacles. And they have areas of calcification: little irregular white dots." When radiologists see tumors with those features, Dr. Goodman said, they "have a high degree of certainty" that the tumor is malignant.

Dr. Goodman emphasizes, however, that no radiologist can be so certain that a tumor that shows up on a mammogram is malignant that he can start treatment without doing a biopsy.

Harmless Cyst Conditions

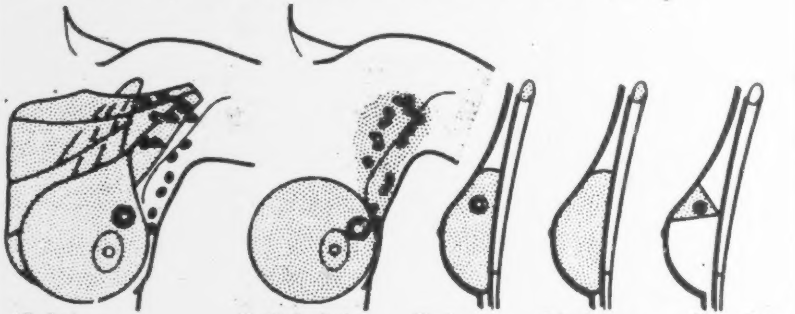
But women who have not reached menopause sometimes have tumors that are so obviously benign that a biopsy is not needed, experts said. These may be harmless cysts or signs of fibrocystic breast disease, a relatively benign condition. In premenopausal women, cells from small tumors with regular edges and no calcification can often be removed through a needle. Physicians can study these cells under a microscope to determine whether they are malignant.

In Mrs. Reagan's case, the lesion is apparently small enough for a needle to be used to mark its location for a biopsy. Guided by the mammography pictures, doctors will press the needle against the lesion, some of which will be removed for biopsy.

The biopsy will be by frozen section. This standard procedure, in which a piece of the tumor is frozen, then sliced and examined under a microscope, gives "a yes or no answer" to the question of whether the tumor is cancerous, according to Dr. Samuel Hellman, phy-

The Types of Mastectomies

Shaded areas indicate what is removed in each procedure. Cancer is designated by black spot.



Radical
Removal of breast, lymph nodes and underlying muscle.

Modified radical
Removal of breast, lymph nodes and nearby tissue. Option chosen by Nancy Reagan, if she has cancer.

Simple
Removal of breast, nipple and skin only.

Subcutaneous
Removal of interior breast tissue. Since procedure is usually done as a preventive measure, no tumor is shown.

Lumpectomy
Removal of cancer and nearby tissue.

Source: American Cancer Society

The New York Times/Oct 17, 1987

sician in chief at Memorial Sloan Kettering Cancer Center in New York.

The procedure that Mrs. Reagan was reported to have decided on if the tumor proves to be malignant is a modified radical mastectomy. With this procedure, surgeons remove the breast and one of the two chest muscles along with lymph nodes from under the arms. The side of the chest where the breast was removed "ends up either flat or slightly curved outward," Dr. Goodman said. He added that with the surgery "the entire procedure is over and done with and the woman is home six to eight days later."

Alternative Procedure

An alternative treatment for breast cancer in which the diameter of the tumor is less than about five centimeters, or two inches, is to remove only the tumor and a few lymph nodes under the arm and to follow the surgery with radiation therapy. Women who opt for this procedure generally have radiation treatment five days a week for five to six weeks.

With the radiation option, the woman's breast is spared and she has very few side effects, Dr. Osborne said. "Months or years later, her breast looks minimally different."

Several well accepted scientific studies have established that the survival for women who select lump removal and radiation is just as good as for women who have radical mastectomies, experts said.

THE NEW YORK TIMES, SUNDAY, OCTOBER 25, 1987

The Exception: Nancy Reagan

Ideas & Trends

The New York Times/Jose R. Lopez

Nancy Reagan waving to supporters who greeted her at the White House Thursday on her return from Bethesda Naval Hospital after surgery for breast cancer.

Advice on Mammograms Is Usually Not Taken

By GINA KOLATA

ABOUT two months ago, Dr. Leonard Davis, a radiologist in private practice in West Los Angeles, offered to do mammograms at the cut-rate price of $50 for women working at a Rockwell International plant in the San Fernando Valley. Dr. Davis, a strong advocate of mammography, the diagnostic technique that detected Nancy Reagan's breast cancer, reasoned that the price would be a strong incentive, since the test normally costs $100 to $150. Because it is a routine screening procedure, insurance ordinarily does not pay for mammography.

The company managers invited Dr. Davis to the plant, put a notice in the company newspaper and informed women employees that they could have the mammograms on company time. All they had to do was make an appointment.

Of 6,000 female employees at Rockwell, six called for appointments. Dr. Davis, dismayed, canceled the screening. "I couldn't afford to do it for just six women," he said.

What happened at Rockwell reflects what is happening nationally, experts say. Only 10 to 15 percent of American women who should have had mammograms have ever had them, according to the American Cancer Society. The society suggests that all women have a mammogram between the ages of 35 and 40, that they have the test every few years between ages 40 and 50, and that they have annual mammograms after age 50.

The method, which uses very low doses of X-rays, can detect tumors before they can be felt and when treatment is most likely to be effective. Since one in 11 American women will get breast cancer in her lifetime, experts say all women should consider themselves at risk. According to Dr. Samuel Hellman of Memorial Sloan Kettering Cancer Center in New York, a Swedish study showed that women with no symptoms had 2 chances in 1,000 of dying of breast cancer within eight years if they had mammograms, and 3 chances in 1,000 if they did not.

Nancy Reagan "was a perfect example" of the value of regular mammograms, said Dr. Robert Wittes of the National Cancer Institute. Her 7-millimeter tumor was too small to be felt, and it was discovered so early that it was still confined to the milk duct where all breast cancers start.

Nancy Reagan's experience does appear to have inspired some women to seek mammograms. The American Cancer Society said it had a 75 percent increase this week in calls from women asking about mammograms. Radiologists said their business was up last week. At Community Radiologists in Silver Spring, Md., for example, about 40 women a day have been calling to schedule mammograms, whereas ordinarily only about 15 a day call. Dr. Davis said the same sort of increase occurred after Betty Ford had breast cancer in 1974 and that after about two months the torrent of calls died down to normal.

Experts say they are at a loss to understand why more women do not have the test, although they suggest several possibilities.

Even well-educated women who can well afford a mammogram put it off. Dr. Davis said some wealthy patients had told him they simply did not know about the test. He pointed out that breast cancer is a perennial topic in women's magazines and newspapers and said he assumes that women simply do not read the articles, perhaps because they do not want to know about this cancer.

Reasons Not to Go

Some women said they put off the test because it did not seem particularly urgent and was time-consuming and expensive. Dalene Barry, a medical writer in Washington, said her gynecologist always suggests that she have a mammogram when she comes in for check-ups. Ms. Barry said she knows full well that she should have one, but she keeps putting it off. "I guess I think I'm immune to breast cancer," she said.

When Mrs Reagan's breast cancer was detected, said Ms. Barry, "it did remind me."

"I said, 'Oh damn, I really ought to do it this year.' But I'm not going to do it this week because they'll be flooded with requests."

Rose Kushner, executive director of the Breast Cancer Advisory Center in Kensington, Md., said having a mammogram, in addition to saving a life, might also save the breast. In light of Mrs. Reagan's decision to have her entire breast removed rather than just the tumor, Mrs. Kushner said she was concerned that many women would now put off mammograms out of fear that even if the test does detect an early cancer, the treatment still will be a mastectomy.

Mrs. Kushner told of a 42-year-old woman she has been counseling to get a mammogram. The woman is at very high risk for breast cancer because her mother died of the disease and her sister has already had cancers in both breasts and has had both breasts removed.

Recently, the woman agreed to have a mammogram. But she canceled her appointment when she heard about Mrs. Reagan. The woman told Mrs. Kushner that she saw no urgency if the treatment would be a mastectomy, no matter how small the tumor is. "If I'm going to lose my breast, I may as well wait a few years longer," the woman said.

THE WASHINGTON TIMES - October 19, 1987

Flood of breast X-rays expected in wake of first lady's operation

By Joyce Price
THE WASHINGTON TIMES

Breast cancer specialists yesterday predicted that Nancy Reagan's malignant breast lesion, detected by a mammogram, will spur strong public interest in an X-ray procedure that up till now has been largely ignored by women most at risk.

"It's likely many of the places that perform mammographies will be flooded in the coming weeks," Dr. Rudolph Almaraz, a breast cancer surgeon at Johns Hopkins Hospital, said yesterday.

Dr. William F. Feller, an associate professor of surgery at Georgetown University Medical Center, agreed. "The major message here is the value of mammography," Dr. Feller said.

"Of all the breast cancer detection methods, mammograms are far superior. Although between 60 and 70 percent of such cancers can be felt in a breast examination, 90 percent can be detected by mammography."

Mrs. Reagan's cancerous lesion of the left breast was only 7 millimeters in diameter — less than a quarter of an inch — too small to be felt. Dr. Feller said her good fortune in having the cancer detected early by mammography came less than a month after release of an important American Cancer Society study on breast cancer screening.

Approximately 40 percent of the more than 4,200 cases of breast cancer found in that study of 280,000 women were detected only by mammograms, Dr. Feller said. "The mammogram is the gold standard. It's the key to everything."

Joann Schellenbach, spokeswoman for the American Cancer Society, said breast cancer is the most prevalent cancer among women today. "One out of every 10 women will develop breast cancer at some time in her life," she said. "We estimate there will be about 130,000 new cases of breast cancer in the United States this year and more than 41,000 deaths."

Women most at risk for breast cancer are those over 40. But Michael S. O'Malley, a breast cancer researcher at the University of North Carolina at Chapel Hill, said recently that many older women are getting neither mammograms nor breast examinations by their physicians. "It's estimated that only between 15 to 20 percent of women over 50 are getting mammographies or having their doctors examine their breasts," he said.

Mr. O'Malley, author of an article on breast cancer prevention in The Journal of the American Medical Association in April, said his study showed that mammography and clinical examination, with followup radiation, reduce mortality by about 30 percent among women age 50 to 59 and by at least 20 percent for women 60 years and older. Because of that, he said, physicians should be encouraging women to have such screening done.

YOUR HEALTH

Dr. E. George Elias, a cancer surgeon at the University of Maryland and collaborator in a major breast cancer study funded by the National Cancer Institute, said the amount of radiation involved in a mammogram has decreased significantly in the past five years. "In fact, it's been reduced to about one-tenth of its former level," Dr. Elias said yesterday. "A mammogram used to require 3 rads of radiation, today only a third of one rad is needed."

Dr. Almaraz and Ms. Schellenbach said they believe many older women avoid mammograms chiefly because of their cost. "Typically, this screening costs between $150 to $200," he said. In an effort to encourage many more women to undergo mammograms, he said, the state of Maryland plans mass mammography screening in April at a cost of $55.

For low-income women, Ms. Schellenbach said, breast self-examination may be the only screening technique available. The American Cancer Society advises a three-pronged approach for prevention of breast cancer, which includes self-examinations at least monthly, clinical examinations and mammograms.

Although mammograms are highly effective in detecting small lumps in the breast, Dr. Feller acknowledged that 10 percent to 15 percent of "really invasive cancers" — or those in which cancer cells can spread to other tissue — are not seen with this procedure. Dr. Elias said he had a patient with a breast lesion 2 centimeters in diameter — far bigger than Mrs. Reagan's — that was not picked up by X-rays. "It's a lie to say mammograms detect 90 percent of all breast cancers," he said. "It's a combination of examination and mammography."

There was general support among the surgeons about Mrs. Reagan's decision to have a modified radical mastectomy, in which her left breast and a portion of any underlying muscle were removed, rather than a less extensive lumpectomy, in which only the cancerous lesion and nearby tissue, would be removed.

Drs. Almaraz and Feller described Mrs. Reagan's lesion as "non-invasive" and "intraductal," meaning it was found inside one of the ducts that carry milk from the glands in the breast to the nipple. "The type of procedure selected often depends on the type of tumor involved," Dr. Almaraz said.

"Although lumpectomies are performed on women with intraductal tumors, they are still considered experimental. If Mrs. Reagan were my patient or wife, I would have supported her decision to undergo a mastectomy. After all, we've had 100 years experience with this kind of surgery."

Pay for breast X-rays due

New law makes insurers liable for older women

By Sue Miller
Evening Sun Staff

Maryland soon will become the first state in the nation to require health insurers to pay up to $100 for breast X-rays for women who are 65 years and older and have no cancer symptoms.

The procedure is known medically as screening mammography. It is important, experts say, because it can detect significant disease up to two years before a doctor or woman doing self-examination can feel it.

But, it's also "widely underused," say specialists who believe the high cost of screening—up to $200—as well as fear may be why many women don't get the test.

The National Cancer Institute, the American Cancer Society and many other groups recommend that women over 50 be screened every year because the incidence of breast cancer has been shown to increase with age, particularly over 60.

Hailed as "landmark" legislation by Maryland radiologists and leaders in women's health care, the new law goes into effect July 1. It was signed into law last week by Gov. Harry R. Hughes. About 80,000 Maryland women would be eligible.

> **‘. . . It's a milestone and a start. Much more needs to be done. But, you can't bite the whole elephant in one mouthful . . .’**
>
> **—Radiologist Clifford Turner**

"It's the first time this kind of law has been mandated by a state legislature," Dr. Clifford Turner, a Silver Spring radiologist who testified during recent legislative hearings on its need, said yesterday.

"It's a milestone and a start. Much more needs to be done. But, you can't bite the whole elephant in one mouthful. It's an indication, however, that Maryland realizes the the need to reach asymptomatic women."

Dr. Robert D. Katz of Pikesville said, "This is great news. Maryland is very progressive. I believe we will be able to do screening more cost effectively if we have higher volumes."

In 1984 and 1985, Mary Rose Okar, a congresswoman from Cleveland, tried unsuccessfully to get federal support for this type of legislation, but Del. Joan Pitkin, D-Prince George's, "got a new law on her first try," said Rose Kushner of Silver Spring, a breast cancer patient, author and nationally recognized lay expert on the disease.

At present, no insurance company pays anything anywhere for screening. The insurers pay only for diagnostic breast X-rays or mammograms to find out the extent of already diagnosed breast cancer.

"By the time you find a mass, mammography does not make a contribution in that breast," said Turner. "It helps the other breast. It makes sure there is no silent cancer there."

Under the law, the screening will be available to women who are on Medicare and have some form of supplemental insurance.

Some 240,000 women have Medicare, but actuaries estimate that only one third or 80,000 will use it to take the test, said Bobbi Seabolt, lobbyist for the Maryland branch of the National Organization for Women.

"We think competition will drive prices down so that more women can afford to take the test," she said.

The legislation, introduced by Pitkin, was backed by NOW, the Maryland Health Coalition and the Maryland Commission for Women.

Oncology Times
VOL. IX, NO. 18
September 15, 1987
THE NEWSPAPER FOR SPECIALISTS IN CANCER

Texas Mammogram Bill Is First To Require Insurance Coverage

By Franca Lebow

AUSTIN, TEXAS—This month Texas women become the first in the country to have their mammograms covered by health insurance. Thanks to the new law recently signed by Gov. Bill Clements, insurance companies will be required to pay for all mammograms—screening and diagnostic—for women over the age of 35 who carry health insurance policies.

Taking effect September 1, the legislation will automatically be written into new insurance policies or renewals as a required clause. The bill was originally sponsored by State Representative Patricia Hill, who believes "the new legislation will not only help save lives, but will also be less expensive for insurance companies in the long run because early detection is less expensive than treatment."

An active lobbyist for the bill was The Susan G. Komen Foundation, a non-profit foundation which supports breast cancer research, educational seminars,

(Continued on page 27)

Texas Governor Bill Clements signs legislation passing nation's first requirement for insurance companies to cover mammography. Behind him at right is Nancy Brinker (with glasses), founder of the Susan G. Komen Foundation, one of the principal supporters of the bill.

Mammogram Bill

(Continued from page 1)

and screening programs. The Dallas-based organization was created five years ago by Nancy Brinker in memory of her sister, who died of breast cancer. Since then Mrs. Brinker herself has suffered from the disease.

She is an astute, determined woman who feels strongly about the oncologist's role in treating breast cancer. "Every woman diagnosed with the disease should see an oncologist," insists Mrs. Brinker, now serving a six-year term on the National Cancer Advisory Board. "But too many oncologists are too conservative in their approach to chemotherapy," she told ONCOLOGY TIMES. "Women would rather be 25% overtreated than 25% undertreated."

The foundation is particularly interested in prevention and established a breast cancer screening clinic at Parkland Memorial Hospital in Dallas two years ago. It was Mrs. Brinker who approached Rep. Hill with the mammogram bill, which is actually modeled after a similar law passed this April in Maryland.

This law states that any women with a Medicare supplemental policy, or "medigap" policy, must be reimbursed for screening mammograms up to $100 annually and it specifies that those mammograms be low-dose. However, the law only applies to women over the age of 65.

And still bottled up in two US House of Representative subcommittees is a national bill which would offer coverage for mammograms as a voluntary insurance option under the Medicare program. The Texas law is by far the most progressive legislation to address the need for insurance coverage for mammography and it is hoped that Texas will indeed set a precedent for the rest of the country.☐

S 1791

Chapter 363.

THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Eighty-seven

AN ACT PROVIDING COVERAGE FOR CERTAIN MEDICAL PREVENTIVE SCREENING TESTS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 175 of the General Laws is hereby amended by inserting after section 47F the following section:-

Section 47G. Any blanket or general policy of insurance described in subdivision (A), (C), or (D) of section one hundred and ten which is issued or subsequently renewed by agreement between the insurer and the policyholder, within or without the commonwealth, during the period within which this premium is effective, or any policy of accident or sickness insurance as described in section one hundred and eight which provides hospital expense and surgical expense insurance and which is delivered or issued for delivery or subsequently renewed by agreement between the insurer and the policyholder in the commonwealth, during the period within which this provision is effective, or any employers' health and welfare fund which provides hospital expense and surgical expense benefits and which is issued or renewed to any person or group of persons in the commonwealth, during the period within which this provision is effective, shall provide benefits for the expense of residents of the commonwealth covered under any such policy or plan for the expense of cytologic screening and mammographic examination. Said benefits shall be at least equal to the following minimum requirements: (a) in the case of benefits for cytologic screening, said benefits shall provide for an annual cytologic screening for women eighteen years of age and older; and (b), in the case of benefits for mammographic examination said benefits shall provide for a baseline mammogram for women between the ages of thirty-five and forty and for a mammogram on an annual basis for woman forty years of age and older.

SECTION 2. Section 110 of said chapter 175 is hereby amended by adding after subdivision (K), inserted by section 1 of chapter 618 of the acts of 1986, the following subdivision:-

(L) Any blanket or general policy of insurance described in subdivision (A), (C) or (D) of this section, which is delivered or issued for delivery within or without the commonwealth and which covers residents of the commonwealth and any employees health and welfare fund which is promulgated or renewed to any person or group of persons in the commonwealth shall provide benefits for expense of cytologic screening and mammographic examinations which are at least equal to the following minimum requirements: (a) in the case of benefits for cytologic screening, said benefit shall provide for an annual cytologic screening for women eighteen years of age and older; and (b), in the case of benefits for mammographic examination, said benefits shall provide for a baseline mammogram for women between the ages of thirty-five and forty and for a mammogram on an annual basis for women forty years of age and older.

SECTION 3. Chapter 176A of the General Laws is hereby amended by inserting after section 8I the following section:-

Section 8J. Any contract, except contracts providing supplemental coverage to medicare or other governmental programs, between a subscriber and the corporation under an individual group hospital service plan which shall be delivered, issued or renewed in the commonwealth shall provide, as a basic benefit to all individual subscribers and members within the commonwealth and to all group members having a principal place of employment within the commonwealth, for expense for cytologic screening and mammographic examination. Said benefits shall be at least equal to the following minimum requirements: (a) in the case of benefits for cytologic screening, said benefits shall provide for an annual cytologic screening for women eighteen years of age; and (b), in the case of benefits for mammographic examination, said benefits shall provide for a baseline mammogram for women between the ages of thirty-five and forty and for a mammogram on an annual basis for women forty years of age and older.

SECTION 4. Chapter 176B of the General Laws is hereby amended by adding the following section:-

Section 4G. Any subscription certificate under an individual or group medical service agreement, except certificates which provide supplemental coverage to Medicare or other governmental programs, which shall be delivered or issued or renewed in the commonwealth shall provide as benefits to all individual subscribers and members within the commonwealth and to all group members having a principal place of employment within the commonwealth for expense of cytologic screening and mammographic examination. Said benefits shall be at least equal to the following minimum requirement: (a) in the case of benefits for cytologic screening, said benefits shall provide for an annual cytologic screening for women 18 years of age and older; and (b), in the case of benefits for mammographic examination said benefits shall provide for a baseline mammogram for women between the ages of thirty-five and forty and for mammogram on an annual basis for women forty years of age and older.

SECTION 5. Section 4 of chapter 176G of the General Laws, as appearing in the 1986 Official Edition, is hereby amended by adding the following sentence: - Such health maintenance contract shall also provide coverage for cytologic screening and mammographic examination as set forth in section forty-seven G of chapter one hundred and seventy-five.

House of Representatives, August 10, 1987.

Passed to be enacted, George Keverian, Speaker.

In Senate, August 13, 1987.

Passed to be enacted, William M. Bulger, President.

August 27, 1987.

Approved,

Governor.

82-843 57

Senator Mikulski. Thank you very much, Ms. Kushner. A couple of questions for you, and then one for Ms. Ireland.

If the Health Care Financing Administration were here, they would, of course, argue cost, and they would also argue that Medicare doesn't pay for any preventive services.

Why should it cover this particular individual one? What would be your response to that issue?

Ms. Kushner. There was a House hearing early in November, and the representative of HCFA said that he would be delighted if Medicare could cover screening by mammography as well as other cancer screens. However, the law that created Medicare prevents the Health Care Financing Administration from paying, reimbursing, for any preventive service except some immunizations, like flu shots.

They would be delighted to start preventing cancer and other diseases. In this country, doctors get paid for treating sickness; they rarely get paid for preventing it. That is one of the problems of our health system. Mammography screening is a place to start preventing.

Senator Mikulski. So your recommendation would be that mammography is an important first step in detecting for cancer of a variety of sorts that strike women and men—be it rectal cancer, colon cancer.

Ms. Kushner. Right.

Senator Mikulski. And we now have the technology, and if people use them, the very nature of increased use would lower the cost.

Ms. Kushner. Yes, that is true. And if more money were spent by the National Cancer Institute and its funded agencies, perhaps more screening tests—the technology you referred to—would be available to detect diseases that are not now detected early, like prostate cancer. There is no screen for prostate cancer, unfortunately. When there is, I will be right here to testify for that.

Senator Mikulski. Terrific. One last question of you because your testimony was so comprehensive. You talked about how in your work on your advisory board you also advocated information and referral services. One of the things seemed to be that women fear, either out of fear or ignorance, even among the most sophisticated, the pursuit of early detection.

Do you have any advice, because one of the things we, of course, could recommend to HHS and other health-oriented Federal agencies is the idea of information as well as referral. Could you offer any suggestions along those lines?

Ms. Kushner. Yes. I feel very strongly that breast self-examination for young women and testicular self-examination for young men should be introduced in the senior year of high school as part of the physical education program, and then in the junior colleges and in college. Women of my age grew up with the feeling that a lump in the breast is a tombstone. There was no early detection; there was no chemotherapy. If you found a breast lump, you were dead.

Testicular cancer is now virtually 100 percent curable, if it is diagnosed early. It is not as much of a problem as breast cancer is, because the incidence is lower. But if a man has it, the incidence is 100 percent for him.

I think education about breast cancer should begin earlier, and this is something I have been advocating on the county and State levels. In Maryland, where Medicare women have been covered since July 1, 1986, if they have Medigap insurance, the pamphlet sent out by insurance companies to participants has a whole page on mammography and its importance.

My own 84-year-old mother-in-law, who has had me with breast cancer for almost 14 years, called me to ask if I thought it would be a good idea for her to be mammographed now that it is covered. She would never have known about it without the booklet from Blue Cross-Blue Shield.

Senator **Mikulski**. Ms. Ireland, you of course are a well-known and highly-regarded actress. My question to you is you work for a living as most other women do, and when they talk about the cost of this legislation, the Federal cost people tell me that if we did annual breast exams through mammogram, it would cost as much as $150 million.

My legislation would of course be every other year as a first step, at $80 million.

But I think that they under-estimate the cost in two ways, and I wonder if this is true. One, not only the cost of x-rays and chemotherapy, the things that you so wonderfully articulated, but also an emotional cost, and the financial cost because of number one, the inability to work; number two, the extra costs other than medical care—the need for support services and so on at home.

If you could talk for a moment or two about both your own experience and also about what you think about ordinary women—do you think ordinary women could get up and go to work every day and go through what you did? Could you talk about that in terms of essentially what it cost you to have cancer in terms of income, production and then other family costs?

Ms. **Ireland**. Well, in answer to your question, do I think that the ordinary woman could get up and go to work, feeling the way I did while I was having chemotherapy, there would be a few days that she would, but a lot of the time, she wouldn't. Of course, chemotherapy is not just one drug; it is many. And some people can work while they are having one of the chemotherapy drugs. I had three, and adriamycin is one of the harshest ones, and I could not have done it.

The emotional cost, of course, we know is devastating to a woman to cut off a part of her body, to amputate a breast. I think I have a very healthy, strong feeling about who I am, and perhaps it hasn't affected me as much as most people, but I speak to a lot of women through the year, and I get many letters every day. Most women are devastated. Most women find their image of themselves as a woman is very damaged by a mastectomy.

Senator **Mikulski**. You feel gouged, don't you? I mean, you feel like your body has been gouged.

Ms. **Ireland**. Oh, yes, absolutely, absolutely. And I think as far as working and insurance, it is very difficult to do many things after you are a cancer victim. If you have to put down on an insurance form, or when you are applying for a job, under illnesses, "Cancer" or medication, "Chemotherapy", people raise an eyebrow and they say, "Well, she's not here for very long. She's a short-term engagement." And they are going to maybe pass you on.

I cannot tell you how much it would mean to women to go through—I have had both experiences—to go through a simple, one-day procedure to take out a lump instead of going through the whole thing that I went through. That is exhausting. I still really haven't gotten my energy back up to full stride.

It is a poison, chemotherapy. The theory is it poisons the cancer cells before it poisons you. And when I said that there were times that I felt if I stopped concentrating and closed my eyes, that I would die, I really felt that way. I couldn't drive a car for myself because I would have to keep stopping and throwing up out of the door. That is how it affected me—and I'm sure I am not alone in that.

So, no. You take women out of the work force; you take women out of whatever they are doing—if they are the elderly, they may be helping a family or taking care of themselves—I think it would be financially advisable in the long range plan—I know I have heard that they think it would cost more to do that now, but looking down the road, it is not just a financial thing. It is an emotional thing for the women of our country, our mothers, sisters, wives, children, future children.

Senator MIKULSKI. I have to announce that there is a vote on as of now on the Hatch amendment related to religious tenets.

And by the way, I would like to introduce my colleague from New Hampshire who has joined us, Senator Gordon Humphrey.

Ms. Kushner, we have to go to the Floor. Did you want to make one last comment briefly, because the clock is running on the vote.

Ms. KUSHNER. Yes. I would very much like to point out that women are not old at 65 anymore. They are not parasites; they pay taxes; they don't just take. The idea that women older than 65 just sit around, babysitting and playing canasta is no longer true.

As far as the reported costs of breast cancer are concerned, I would like to point out that the National Center for Health Statistics has absolutely no idea of what they are. So many costs are not reported to any agency—costs like parking fees, travel, prescription drugs, household help—that it is impossible to know the total expense of breast cancer to a patient.

I have been trying for years to get data on these costs of having breast cancer, but there simply are no data available. So most costs are under-reported, because they are not covered by anybody except the woman's personal pocket.

Senator MIKULSKI. Well, thank you, Ms. Kushner.

Regrettably, we are going to have to recess. I'd like to thank both of you for telling us, not only from the standpoint of statistics—when somebody says 40,000 people will die, "x" number of thousands have had this—you have put a human face on a national problem, and hopefully, it will motivate the Congress to do more.

Thank you very much for coming.

Ms. KUSHNER. Thank you.

Ms. IRELAND. Thank you.

Senator MIKULSKI. This hearing stands in recess for 15 minutes.

[Short recess.]

Senator **Adams** [presiding]. The hearing will resume.

I have voted; Senator Mikulski is on her way to vote. So that you all understand, as a former Secretary of Transportation, the car going over to the Capitol is broken, so it takes a little extra time.

But we want to proceed, because we have a number of witnesses that we wish to hear from this morning. This is a terribly, terribly important time for all of us, so we want to be certain that we use our time as profitably as possible.

I was going to say I want to apologize to you for not being here at the opening, but I can't apologize for having been over in the INF hearings because I am part of that Committee, too, and I have a great belief that if we blow up the world or poison the world that a number of other things become secondary. So I wanted to be there for the opening of that. But I do give you my apologies for not being here when it started. As you know, the hearing this morning will be divided into two parts. Senator Mikulski will continue with the mammogram and the entire breast cancer discussion; then we will shift to the matter of the Pap smears and the whole problem we have in cytotechnology.

So I wanted you all to know that we are on schedule, we will continue, and all of you who have been here before understand that that is kind of the way the Senate operates, that we have to do votes and Committees at the same time. It in no way indicates that we are not extraordinarily dedicated to seeing that something happens in these two fields.

Now, I would like to ask the second panel to come up. Senator Mikulski requested that I do that. I have a statement I would like to read on behalf of Senator Hatch as I am introducing Dr. Smart. So if Dr. Smart, Dr. Strax, Dr. Melillo—and if I mispronounced that, I apologize—would please come forward with the additional ones that you wish to have with you, Senator Mikulski will be back in a moment.

I would like to start first by reading a statement by Senator Hatch, who is on the floor with Title IX, the Civil Rights Restoration Act, bill at the moment.

And Dr. Smart, I would introduce you on behalf of Senator Hatch as follows.

> It is indeed my pleasure to welcome before the Committee Dr. Charles Smart. He is a renowned cancer surgeon/researcher, and hails from my home State of Utah.
>
> Dr. Smart has directed much of his research efforts to studying cancer in Utah, but his influence and expertise is recognized nationwide.

Dr. Smart, while Senator Hatch misses you in Utah, we are honored to have you here, carrying on as a leader of the National Cancer Institute.

Dr. Smart has served as a member of the Board of Directors both on a regional and national scale of the American Cancer Society. He is currently Chief of the Community Oncology Programs at the Division of Cancer Prevention Control at the National Cancer Institute. Dr. Smart has to his credit over 100 scientific publications on cancer, with special emphasis on cancer detection and screening.

Our Committee is indeed fortunate to hear from Dr. Smart, and we all appreciate his willingness to share his expertise on the importance of the early detection of cancer.

Dr. Smart, Dr. Strax, Dr. Melillo, we welcome all of you.

Dr. Smart, if you wish to start and then if you will all give your opening statements, Senator Mikulski will return in a moment, as will other Senators.

STATEMENT OF DR. CHARLES R. SMART, CHIEF, EARLY DETECTION BRANCH, DIVISION OF CANCER PREVENTION AND CONTROL, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD; DR. PHILIP STRAX, CLINICAL PROFESSOR OF ONCOLOGY AND RADIOLOGY, UNIVERSITY OF MIAMI SCHOOL OF MEDICINE, MIAMI, FL; AND DR. DIXIE MELILLO, CHAIRMAN, DEPARTMENT OF SURGERY, PASADENA BAYSHORE MEDICAL CENTER, HOUSTON, TX

Dr. SMART. Mr. Chairman and Members of the Committee. I am Charles R. Smart, Chief of the Early Detection Branch. My Branch is responsible for identifying, evaluating and encouraging early cancer detection procedures in the United States.

It is a privilege for me to be here today to discuss the early detection of breast cancer. Breast cancer is the leading cancer in women. Since all of the statistics have been given about it, I am not going to repeat those except to say that the incidence has been increasing over the past 30 years, approximately one percent per year, and it is the leading cause of death from cancer in women today in the United States.

Increasing age is the most common risk factor. As women get older, breast cancer increases dramatically, especially beginning at the age of 40, as one can see in my hand-out on Table 2.

The detection of breast cancer at an early stage strongly influences the success of treatment. Minimal breast cancers are 100 percent curable when treated by surgery, including lumpectomy, with or without radiation. Current data from the National Cancer Institute show that only 49 percent of women detected with breast cancer have localized disease at the time of diagnosis, which means that over half of women have more advanced disease at the time of diagnosis.

The relative five-year survival rate for white women with localized cancer of the breast is over 90 percent at the present time; when they have regional disease, 69 percent; and then they have distant disease, 18 percent, are alive at five years.

Mammography is a most effective method for detecting early-stage breast cancer. It requires an examination before the patient or the physician are aware that there is a problem; before there are symptoms, such as a lump.

In the past, early detection of breast cancer meant the detection of localized disease. Now it means the detection of minimal disease. Minimal cancer is *in situ* or invasive cancer under one centimeter. Ordinarily, because of their small size, these cancers cannot be found by the patient or her physician, but are detected on mammography.

At the present time in the United States, only 9 percent of women that are presently detected have minimal breast cancer.

In 1963, Shapiro and Strax, Dr. Strax being next to me, organized a randomized early cancer detection trial in the Health Insurance Plan of Greater New York called the HIP Study. Sixty-two thousand women 40 to 64 years of age were randomized into a study group who were offered four yearly mammograms and a physical examination of the breast by a physician, and the control group received the usual medical care. At six years from entry into the study, there was a 30 percent reduction in mortality from breast cancer in women over 50 years of age. Now, at 18 years follow-up, I as well as others believe that there is an equal benefit for those in the age group 40 to 49. Two other studies from Sweden and one from the Netherlands have shown similar benefit in women over 50 years of age.

In 1973, the National Cancer Institute and the American Cancer Society organized what was known as the Breast Cancer Demonstration Project, the BCDDP. Twenty-nine breast cancer centers across the country each enrolled 10,000 women, 35 to 74 years of age, for a total of 280,000 screenees. They were offered five yearly mammograms plus a breast examination. Of the 3,548 cancers detected, one-third were minimal breast cancers, and 80 percent were classified as localized disease. That contrasts with the 9 percent of minimal disease that we are seeing at the present moment in this country to have one-third, or 32 percent, being minimal cancers. Instead of 49 percent being localized, having 80 percent localized disease is progress in early detection which translates into improved survival. For all screening-detected cancers in this project, there was a 91 percent, five-year survival rate and an 81 percent ten-year survival rate.

Mannography has improved dramatically between the Sixties' HIP study and the Seventies' BCDDP in its ability to detect breast cancer. In women 40 to 49 years of age, detection by mammography increased from 40 percent in the HIP study to 90 percent in the BCDDP and in women over 50, it increased from 60 percent in the HIP study to 90 percent in the BCDDP, making the detection of breast cancer equal between these two age groups.

The detection of minimal cancers was increased from 8 percent in the HIP study to 32 percent in the BCDDP. There was also a decrease of six- to ten-fold in radiation dosage. At the present time, it is felt that the risk from radiation is negligible.

In conclusion, Mr. Chairman and Members of the Committee, I would like to say that if the benefits from the Early Detection Demonstration Project of the BCDDP were transformed to the women of America, it would result in a 46 percent decrease in mortality rate.

Unfortunately, only 15 percent of women at the present time over 40 years of age have had a mammogram. This is regrettable.

Thank you very much for allowing me to testify, and I would be glad to answer any questions.

[The prepared statement of Dr. Smart follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

RELEASE ONLY UPON DELIVERY

STATEMENT OF CHARLES R. SMART, M.D.
CHIEF, EARLY DETECTION BRANCH
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NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE
THE

SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

JANUARY 28, 1988

Mr. Chairman and Members of the Committee:

I am Charles R. Smart, M.D., Chief of the Early Detection Branch in the Division of Cancer Prevention and Control of the National Cancer Institute. My branch is responsible for identifying, evaluating, and encouraging the implementation of effective early cancer detection procedures in the United States

It is a privilege for me to be here today to discuss the early detection of breast cancer. Breast cancer is the leading cancer in women, with an estimated 130,000 new cases and 41,000 deaths annually. It is responsible for more new cases of cancer among women than any other cancer. It is also the leading cause of cancer death among American women. One of every 10 women in the United States is expected to have breast cancer some time in her life . The incidence has been increasing over the past 30 years, at a rate of one percent per year (Table I). A personal history of breast cancer or a family history of breast cancer in a mother or sister increases a woman's risk by two or three times. Women with these high risk factors make up 15 percent of all women with breast cancer. Increasing age is the most common risk factor. As women get older, breast cancer increases dramatically, especially after 40 years of age (Table II).

Table I

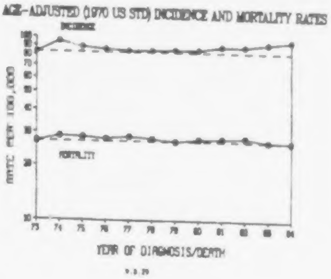
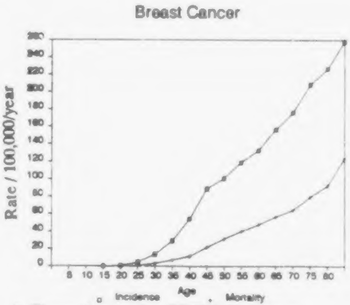


Table II

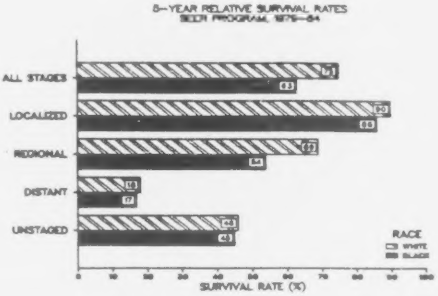


* Data from the SEER Program

Detection of breast cancer at an early stage strongly influences the success of treatment. Minimal breast cancers are nearly 100 percent curable when treated by surgery (including lumpectomy), with or without radiation. Current data from the National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program for the period from 1979 to 1984 show that of newly diagnosed women, only 49 percent had localized disease at diagnosis, 41 percent had regional, 7 percent distant and 3 percent unstaged disease. The relative five-year survival rates for white females by stage were: localized 90 percent; regional 69 percent; and distant 18 percent (Table III).

Table III

Breast Cancer



Mammography is the most effective method for detecting early stage breast cancer. Detection of early breast cancer requires examinations before the patient or the physician is aware that there is a problem, before there are symptoms, such as a lump. Such examinations in people who have no symptoms are referred to as screening examinations. Minimal breast cancers often are included as a subgroup of the localized stage. They made up 9 percent of all cases diagnosed from 1973 to 1984. Minimal breast cancer has only been recognized as a special category in the past 12 years, with the widespread use of mammography. This group has been defined as including all non-invasive or in-situ cancers plus invasive cancers under 1 centimeter in diameter. Ordinarily, minimal cancers cannot be discovered by the woman or her physician because of their small size but are most frequently detected by mammography.

In 1963, Shapiro and Strax, organized a randomized early breast cancer detection trial in the Health Insurance Plan of Greater New York (HIP) Approximately 62,000 women 40 to 64 years of age were randomized into a study group to be offered 4 yearly mammograms and physical breast examination and a control group that were to continue usual medical care.. At six years from entry into the study there was evidence of a 30 percent reduction in mortality from breast cancer in women over 50 years of age who were offered screening, as compared to the control group. Now at 18 years followup, I, as well as others, believe there is an equal benefit for those in the 40-49 year age group. Two other studies, one from Sweden and one from the Netherlands, have shown similar benefit in women over 50 years of age.

In 1973 , the National Cancer Institute and the American Cancer Society began a Breast Cancer Detection Demonstration Project (BCDDP) . 29 breast cancer detection centers across the country each enrolled ten thousand women 35-74 years of age , for a total of more than 280,000 screenees. They were offered five yearly mammograms plus a breast examination by a physician or nurse. Of the 3,548 breast cancers detected as a result of the screening project, one third were minimal cancers and eighty percent were classified as localized disease, having no lymph node involvement. Survival rates for all the screening-detected cancers were exceptional, 91 percent at five years and 81 percent at 10 years, similar to that seen in the SEER program for localized cancer.

Mammography has improved dramatically between the 1960's HIP study and the 1970's BCDDP in its ability to detect cancer. In women 40-49 years of age detection increased from 40% to 90% and in women over 50 it has increased from 60% to 90% making detection as accurate for women age 40-49 as for 50 and over. The detection of minimal cancers has increased from 8% to 32.4%. There has been a 6-to-10 fold decrease in radiation dosage. At present, the radiation risk is considered to be negligible in comparison to the benefits for all women 40 years of age and older (Table IV).

Table IV

Improvements in Mammographic Cancer Detection

	1960's HIP		1970's BCDDP	
	40-49	50-59	40-49	50-59
Modality Detect				
% Mam. only	19.4	41.5	45.3	46.7
%Mam. + P.E.	19.4	18.5	45.7	45.3
%P.E. only	61.3	40.0	8.0	6.6
Minimal Cancer	9%		32.4%	
Radiation Dose	3.2 rad		0.2-0.7 rad.	

In conclusion, Mr. Chairman and members of the Committee;

(1) Breast Cancer is the major cancer problem for American Women.

2) Mammography in asymptomatic women is the most effective method of early detection.

3) With the improvements which have occurred in mammography, the risks from radiation are now negligible

(4) If modern mammography were applied broadly in the United States to the population of women over 40, there is good reason to believe that mortality from breast cancer would decrease by 30 to 40 percent and where applied to older age groups the benefits would be even greater.

Thank you very much for allowing me to testify, and I would be glad to answer any questions.

Senator **Adams**. Thank you, Dr. Smart.

We will withhold on questions until all members of the panel have made their opening statements, but thank you very much for an excellent statement.

Dr. Strax?

Dr. **Strax**. Thank you for the chance to talk about my favorite subject. My name is Dr. Philip Strax. I have been a pioneer in the early detection of breast cancer as a way of saving women's lives for the past 30 years.

As you have heard, the cancer that women fear most is that of the breast, and with good reason. Statisticians tell us that one woman out of ten in this country is destined to develop the disease in her lifetime, and even more unfortunately, the majority of such women will succumb to the disease within five years.

The disease is uncommon in women under 35, but increases in frequency with age. At least one-third of the cancers are in women over 65.

We don't know the cause of breast cancer, nor do we have any method to prevent its occurrence. We do not as yet have the magic bullet or medicine to cure the disease at any stage.

It is general knowledge that detection of breast cancer in the localized stage with negative nodes leads today to an over 87 percent, five-year survival rate. When nodes are involved, the survival rate drops to 53 percent or less. This is the stage at which the majority of breast cancers are detected today.

The secret of success in breast cancer treatment may lie at the stage at which intervention is introduced. If breast cancer is found and treated when localized, and the disease can be completely removed at a time when immunocompetence is intact, the cure rate may be high. But the optimum time for detection at this most curable stage may be before the woman is aware of a problem or even before the lesion is palpable by woman or physician. Such a cancer may be detectable only in mass screening.

In short, the object of screening for breast cancer is to discover those among the apparently well who are in fact suffering from disease.

What was needed in the breast cancer problem was acceptable evidence that there was indeed a stage at which detection of the disease would result in a sufficiently long-term survival that could be equated in practical terms with reduced mortality. We had to know that early detection of breast cancer can actually save lives, not just mean that we find it earlier.

The mass screening program for breast cancer detection of the Health Insurance Plan of New York was developed under contract with the National Cancer Institute in 1962, at a time when the death rate from disease had been stationary for some 30 years and when there was a revived interest in mammography as an effective modality to detect breast cancer in a non-palpable stage. Sixty-two thousand apparently well women age 40 to 64, belonging to 31 medical groups, were divided into two carefully matched groups. One group of 31,000 was designated as the study group and received an initial examination and then three annual examinations consisting of an independent clinical examination by the surgeons of the groups and mammography done with the best technique available at the time. The matched control group of equal size was followed through records. About the same number of cancers developed in both groups. But it became apparent after five years that fewer women died of breast cancer in the study group than in the control. This difference has persisted. After 18 years of careful follow-up, about 25 percent fewer women with breast cancer have died in the study group compared to the control. Similar results, although with not quite as long a follow-up, have been reported from Sweden and The Netherlands.

The basic procedures used in mass screening are an interview to develop demographic data, such as ethnic background, education, parity, and so on, to develop clues to increased risk; a careful clinical examination—and this is a must—by a physician well-versed in the procedure or by a paramedical person after proper training and under the guidance of a clinician; teaching of breast self-examination, preferably on a one-to-one basis, with emphasis on its importance on continuing performance; and mammography, or soft tissue x-ray examination of the breast.

Mammography, which is at least 70 years old, has been considerably refined and brought to a high degree of technical excellence. Use of special dedicated machines with molybdenum anode tube and compression has made possible the use of special fast films with rare earth screens which produce mammograms of excellent quality with markedly reduced radiation dosage, from 8 to 12 R as in the HIP study, down to less than .5 R to the skin, and less than .05 rad to the mid-breast for the two views generally used.

The improved mammographic techniques have resulted in a substantial increase in cancers found on mammography. Improvement in technique has continued and is continuing. And yet, less than 15 percent of women in this country have ever had a mammogram and the type of proper palpation needed to achieve success.

What are the obstacles?

First, the fear of radiation. For many years, it has been known that the breast is sensitive to x-rays. In 1976, a commotion developed and statements were made and reported at length in the media that mammography, which uses x-rays, might in itself produce breast cancer, and the hazard might be greater than the benefit. Concern over hazard from x-radiation in mammography has been sadly over-rated, and has led to unnecessary and unreasonable fear that the procedure itself could cause harm.

Many studies by authorities have concluded that the risk from mammography, if any, is dependent on the age of the woman and the dose of the x-rays given. There is no evidence of significant hazard in women over 35, the age at which periodic mass screening is suggested. The dose from modern mammography continues to be reduced and is so small that any hazard from periodic mammography even over many years must be considered negligible and probably not even measurable. Certainly, the potential benefit from mammography far exceeds any theoretical hazard.

A second obstacle is the cost of examination. The cost of examination, including mammography, is of little importance when examining the comparatively few markedly symptomatic women met in general practice. However, when larger numbers of asymptomatic or minimally symptomatic women are involved, as in mass screening, especially when they are in a low-income bracket, the cost of the procedure, especially that of mammography, becomes important. In general, community mass screening involves the use of dedicated personnel under the auspices of a nonprofit or low profit center, using many volunteers and medical personnel imbued with a sense of dedication and even personal sacrifice for the satisfaction of saving women's lives.

A few such centers are in operation in this country and act as examples of what can be done when the will and proper attitude are available. Noteworthy are the Guttman Institute in New York City, where a minimal charge of $45 is made, and where about 40,000 women are examined every year, and the Strax Institute in Fort Lauderdale, Florida, where a charge of $35 is made for the complete examination, including thorough clinical examination as well as mammography. There, about 30,000 women are being examined every year.

A third problem, and perhaps a very important one, is motivation. Perhaps the most important factor in making mass screenings successful is motivation of women to accept the procedure. Success in saving lives through mass screening is in direct proportion to the numbers of women attracted and stimulated to participate. If mass screening is the only means we have to save lives from the disease, women's groups must be in the forefront to demand such procedures as is their right. Physicians must be willing to realize that it is their duty to alert women to the danger and make possible implementation to overcome it. Motivation of women to accept and even demand screening for breast cancer needs to be developed. Effort in this direction must be ongoing and persistent and relate to the population involved.

The educational feature of mass screening varies in different communities, with different ethnic groups and cultural backgrounds. Awareness of the program needs to be promoted. The centers for such screening must be readily available and easily accessible.

The American Cancer Society and its volunteers have had an excellent input into such activities by making available the use of the media and by stimulating direct neighborhood efforts.

Physicians need to be impressed with the value of complete breast examination, including mammography in periodic screening as the only practical means available at this time to save lives of women from the disease.

In conclusion, most women with breast cancer could be saved by detection of the disease in an early, more curable stage if physicians would teach their patients to examine their breasts properly once a month, and, this is most important, to encourage them to have complete periodic breast examinations, to include mammography, according to American Cancer Society guidelines.

Perhaps it is now time that concerns over risk in screening women should be allayed. Perhaps more attention should now be paid to the remaining problems of screening, such as cost of screening, detection of true high-risk factors, and methods for improving motivation.

The problem of breast cancer as the number one cancer in women, with its substantial mortality and its stationary death rate, is still very much with us. Present evidence that detection of early breast cancer results not only in increased survival, but even more importantly, in the possibility of much smaller surgical procedures and decreased death rate, seems to make it imperative that we move ahead with screening activities by making it a more effective, more practical and more acceptable to all women and their physicians.

Medicare coverage of breast examination, including mammography, and including the apparently well woman, would be an important contribution to improving motivation and go a long way to saving lives of women from breast cancer.

And may I also add, it is essential that women who have been motivated to have the screening examination be convinced that the examinations are being done in an accurate, efficient manner, and they are comfortable and safe. A noteworthy ongoing step in this direction has been taken by the American College of Radiology to address this problem. A quality assurance program has been developed by a group of radiologists, physicists and clinicians that involves a detailed questionnaire relating to the facility being studied plus actual physical measurements of the mammographic techniques being used.

Centers with acceptable guidelines will be listed in each State for public scrutiny. In this way, a woman entering a screening study can be assured of the best, complete examination available today.

Thank you.

[The prepared statement of Dr. Strax follows:]

TESTIMONY OF DR. PHILIP STRAX

BEFORE THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

JANUARY 28, 1988

MASS SCREENING TO REDUCE MORTALITY FROM BREAST CANCER

Philip Strax, M.D.

The cancer that women fear most is that of the breast - and with good reason. Statisticians tell us that one woman out of ten in this country is destined to develop the disease in her lifetime and even more unfortunately, the majority of such women will succumb to the disease within five years. The disease is uncommon in women under 35, but increases in frequency with age. About one-third of the cancers are in women over 65.

We do not know the cause of breast cancer, nor do we have any method to prevent its occurrence. We do not as yet have the magic bullet or medicine to cure the disease at any stage.

It is general knowledge that detection of breast cancer in a localized stage with negative nodes leads today to an over 87%, five year survival rate. When nodes are involved, the survival rate drops to 53% or less. This is the stage at which the majority of breast cancers are detected today.

The secret of success in breast cancer treatment may lie in the stage at which intervention is introduced. If breast cancer is found and treated when localized, and the disease can be completely removed at a time when immunocompetence is intact, the cure rate may be high. The optimum time for detection at the most curable stage may be before the woman is aware of a problem or even before the lesion is palpable by woman or physician. Such a cancer may be detectable only in mass screening.

In short, the object of screening for breast cancer is to discover those among the apparently well who are in fact suffering from disease.

What was needed in the breast cancer problem was acceptable evidence that there was a stage at which detection of the disease would result in a sufficiently long term survival that could be equated in practical terms with reduced mortality.

The mass screening program for breast cancer detection of the Health Insurance Plan of New York was developed under contract with the National Cancer Institute in 1962 at a time when the death rate from the disease had been stationary for some 30 years and when there was a revived interest in mammography as an effective modality to detect breast cancer in a non-palpable stage. Latest data indicates a 25% reduction in mortality after 18 years of follow-up.

The basic procedures used in mass screening are an interview to develop demographic data, such as ethnic background, education, parity, menstrual and breast history to develop clues to increased risk; a careful clinical examination by a physician well-versed in the procedure or by a paramedical person after proper training and under the guidance of a clinician; teaching of breast self-examination, preferably on a one-to-one basis with emphasis on its importance on continuing performance; mammography or soft-tissue x-ray examination of the breast. This procedure which is as least 70 years old, has been considerably refined and brought to a high degree of technical excellence. Use of special dedicate machines with molybdenum anode tube and compression has made possible the use of special fast films with rare earth screens which produce mammograms of excellent quality with markedly reduced radiation dosage, from 8-12 R as in the HIP study down to less than .5 R to the skin and less than .05 rad to the mid-breast for the two views generally used.

The improved mammographic techniques have resulted in a substantial increase in cancers found on mammography. Improvement in technique has continued and is continuing. And yet, less than 15% of women in this country have ever had a mammogram and the type of proper palpation needed to achieve success.

For many years, it has been known that the breast is sensitive to x-rays. In 1976, a commotion developed and statements were made and reported at length in the media that mammography which uses x-rays, might in itself produce breast cancer, and the hazard might be greater than the benefit. Concern over hazard from x-radiation in mammography has been sadly overrated and has led to unnecessary and unreasonable fear that the procedure itself could cause harm.

Many studies by authorities have concluded that the risk from mammography, if any, is dependent on the age of the woman and the dose of x-rays given. There is no evidence of significant hazard in women over 35, the age at which periodic mass screening is suggested. The dose from modern mammography continues to be reduced and is so small - down to less than 0.05 rad to the midbreast - that any hazard from periodic mammography even over many years must be consider negligible and probably not even measurable. Certainly, the potential benefit from mammography far exceeds any theoretical hazard.

The cost of examination, including mammography, is of little importance when examining the comparative few markedly symptomatic women met in general practice. However, when larger numbers of asymptomatic or minimally symptomatic women are involved, as in mass screening, especially when they are in a low income bracket, cost of the procedure, especially that of mammography, becomes important. In general, community mass screening involves the use of dedicated personnel under the auspices of a non-profit or low profit center, using many volunteers and medical personnel imbued with a sense of dedication and even personal sacrifice for the satisfaction of saving women's lives. A few such centers are in operation in this country and act as examples of what can be done when the will and proper attitude are available. Noteworthy are the Guttman Institute in New York City where a minimal charge of $45.00 is made and the Strax Institute in Fort Lauderdale, Florida, where a charge of $35.00 is made for the complete examination, including thorough clinical examination as well as mammography. /

Physicians need to be impressed with the value of complete breast examination including mammography in periodic screening as the only practical means available at this time to save lives of women from the disease.

Perhaps it is now time that concerns over risk in screening women should be allayed. Perhaps more attention should now be paid to remaining problems in screening; such as cost of screening, detection of true high risk factors and methods for improving motivation. The problem of breast cancer as the number 1 cancer in women, with its substantial mortality and its stationary death rate, is still very much with us. Present evidence that detection of early breast cancer results not ony in increased survival, but in the possibility of much smaller surgical procedures, seems to make it imperative that we move ahead with screening activities by making them more effective, more practical and more acceptable to all women and their physicians.

Medicare coverage of breast examination, including mammography, in all women, including the apparently well woman, would be an important contribution to improving motivation and go a long way to saving lives of women from breast cancer./

* * *

Senator **Adams**. Thank you, Dr. Strax.

Senator Mikulski, I am pleased you are back, and I turn the hearing over to you, Madam Chairman.

Senator **Mikulski**. Thank you, Senator Adams. I was late getting back because there was only one subway operating between a couple of buildings here.

For those who might not be aware, Senator Adams is also the cosponsor of my legislation and a real leader in this cancer detection among women.

Dr. Melillo, I would like to welcome you to testify, and I understand you are the Chair of the Department of Surgery at the Pasadena Bayshore Medical Center, in Houston, Texas. And since you and I both fill non-traditional roles, I feel a special kinship with you. But we are looking forward to your testimony.

Dr. **Melillo**. I want to thank you very much for allowing me to come here and speak with you.

I am a general surgeon, and I specialize in disease of the breast and breast cancer. As a result, I deal with a lot of women who go through the trauma of this disease.

I was asked to put together some figures about the cost of dying from advanced breast cancer. In my hand-out, you will notice that the hospital charges, even though they are very high, are only the hospital bill. They do not include the cost of radiation or the cost of chemotherapy. They do not include the physicians 'fees. And still, they are quite exorbitant.

I was impressed to see in the OTA report that their cost of dying from advanced breast cancer was only about $10,000. We have not been able to keep it down that low.

I think the most important thing is that about five or six times a year, I have to sit with a woman who is drowning in her own fluid, or coming in with broken bones because she has got advanced breast cancer.

"E.A." is the first patient here. She ran up a $52,000 hospital bill, but that somehow just does not tell about her pain and suffering and her family's suffering.

I think the hardest thing is sitting there, watching these women die, and realizing that at least 50 percent of them did not have to die; We really could have diagnosed this cancer earlier and cured it. I happen to believe it is probably going to be higher than 50 percent if we really had a good screening program going.

I would like to show you some slides, if I might. Most of the statistics have already been covered, and I am sure you are inundated in statistics, but I would like to show you what a mammogram is so you can really get a good feel for it.

[Slide presentation.]

Dr. **Melillo**. The first things are just statistics. As you know, breast cancer is increasing, but a very important fact is that over the last 50 to 60 years, we have not reduced the mortality rate from breast cancer. The incidence increases; the mortality rate has remained a flat line.

We do have the ability to decrease that mortality rate, and we are not using it. Now, as you already know from the testimony that has been given, the Medicare population is at the highest risk. You are dealing with the highest-risk group of women that exists.

The BCDDP project has been quoted, and it, like so many other projects, has shown that we definitely can reduce the mortality rate.

I think a very important fact to bring up is that breast cancer is slow-growing. For the most part, it takes about seven years, and some studies quote up to ten years, to reach the size of one centimeter. So what that really means is that we have all the time in the world to find it if we look for it.

Under the size of one centimeter, it is very difficult to distinguish a breast cancer from the normal nodularity of the breast. So it really has to be about the size of one centimeter to find it.

Now, the beauty of the mammogram is that you can see that breast cancer about three years before you can feel it, and that is when it is curable. That is when it is important to catch it.

Now, this is a mammogram. I do not know how well you can see this slide. But this is a lateral view of the breast. The arm is up above, the nipple, the ribs and the chest wall. This is a mammogram of an older woman, and it is a beautiful window to see through the breast.

This is a mammogram with a large cancer. Obviously, we do not need the mammogram to find this cancer. You can feel this cancer. And this is not at the stage that we want to find them.

But this is a very large breast with a six-millimeter, six-tenths of one centimeter cancer, about the size of Mrs. Reagan's cancer, in it.

Senator **MIKULSKI.** It looks like a button, with those little——

Dr. **MELILLO.** Well, yes. It has red lines around it, so it makes it a little easier to find.

The reason that we took this little dot out of this lady's huge breast—and it had to be localized; you cannot feel it—two years ago, this same woman had a three-millimeter dot in her breast in the same place, two years before this mammogram. And when it changed from three millimeters to six millimeters, we decided it had to come out.

Now, obviously, in retrospect, it would have been nice to have taken it out two years ago. But still, this was a six-millimeter cancer; no evidence of spread to the nodes. This lady did not lose her breast. She is doing well three years later and probably will continue to do well. But this is an absolutely fantastic modality to save women's lives if we use it.

Another thing—it is an unpleasant thought, but I think it is very, very important that people realize what happens to breast cancer if you do not catch it early. The next couple of pictures are not very pleasant. These are my patients, and these are women that I have to deal with. I think you need to know what happens to breast cancer. It just doesn't stay real nice and pretty in the breast. These next pictures are a little bit graphic and unpleasant.

This lady is a lady I took care of in January, and she is a Medicare patient. This is a far-advanced disease that has been there about 10 to 15 years, out of the skin. She died about seven days after this picture was taken. She came in because she could not breathe. Her lungs were filled with fluid, and she suffocated, she just died.

And if you asked her, "Why didn't you take care of the thing on your chest?" she said, "Well, it didn't hurt." And it doesn't hurt while it stays in the breast. It hurts when it gets in the spine and it paralyzes you, and it hurts when it gets in the brain, and it compromises the space up there. But when it is in the breast, it really doesn't hurt, so many women tend to ignore it.

This next picture is even worse, I'm afraid. This is what can happen if you don't take care of it. It doesn't simply go away. It can cause a lot of pain and misery and grief before you die. And this all can be avoided.

Dealing with these women day in and day out is why I have kind of formed my one-woman campaign in the Houston area to educate women, to tell them of the value of mammography.

In my hospital, we were doing three mammograms a week, and I simply did not feel—I was seeing advanced breast cancer, I was seeing stages that you know that at the most the woman had six months to two years to live—and I decided that women are not stupid, and that if they knew about this, they would take advantage of it.

We worked out a deal where I would go out and give talks if the hospital would lower their price on the mammography, and at that particular hospital now it is $80. But I gave talks. We went from doing three a week to ten a day. And in the last week alone, I did two breast cancers that could only be seen on mammogram and had to be localized.

So I know this works, and it is very, very important. In my experience in asking high-risk women to get mammograms—and Jill Ireland brought this up—when they have to take that money out of their pocket to get a test that may or may not show anything, and when they are on fixed incomes, it is very hard to convince a woman to do that.

Of course, most of them, after seeing my talk with some of these pictures decided it is probably more important. But I think it would be of great benefit in saving women's lives and in saving suffering, because one out of ten, you just have a look around, and it is going to be someone in your family or someone you know. I think it is a very important thing, and I think we need to try to get this legislation passed.

Thank you.

[The prepared statement of Dr. Melillo follows:]

TESTIMONY OF DR. DIXIE MELILLO

BEFORE

THE LABOR AND HUMAN RESOURCES COMMITTEE OF THE U.S. SENATE

JANUARY 28, 1988

MAMMOGRAPHY SCREENING vs THE HIGH COST OF DYING

The American Cancer Society has endorsed mammography screening by stating that it has proven to be the most effective tool in the early detection of breast cancer.

But mammography screening is of little value if women do not use it. One of the biggest problems we, in the medical profession, encounter is recommending a "screening" procedure which customarily costs at least $100 and may run as high as $160 to $200.

Medicare does not provide coverage for mammography screening viewing it as "preventative medicine," but it will pay for mammography after a palpable mass has been found in the breast. At this point it is usually too late.

To cure breast cancer it must be detected early, preferrably before it has advanced to the palpable stage. Studies have clearly shown that a cancerous mass can be seen on mammograms as much as three years before it can be felt. When treated at this stage there is a 95% cure rate.

In the most comprehensive study of its type, the Breast Cancer Detection and Demonstration Project (BCDDP), which screened 280,000 asymptomatic women (women who had no symptoms of cancer, no family history, no palpable masses) 3,700 early cancers were detected. This project also proved that mortality could be decreased by 50% if asymptomatic women were routinely screened. This is an important finding because there has not been a decrease in the mortality rate in breast cancer for eighty years.

The overwhelming response from women to the Texas Breast Cancer Screening Project, a campaign launched by the American Cancer Society in February of 1987, is an obvious indication that women are becoming better educated about the importance of early screening. In the Houston area alone, over 25,000 women took advantage of this project which offered screening at a special low price of $50, proving that if mammography screening were affordable women would use it. I realize, however, that for many medicare aged women taking even $50 from a small fixed income would impose a hardship.

I am convinced that in the future the price of mammography will become affordable for most women. Until that time, which could be many years away, there are thousands of women who today would benefit from this screening if medicare would cover the cost of it.

Although there are some who would argue the "cost effectiveness" of screening women who are 65 years or older, we must recognize that it is this exact age group which represents the women who are at the highest risk. Early detection is as critical at this time as any other in a woman's life and when we consider the life expectancy rates for women in the United States, early detection could mean the difference in many healthy years of living.

Perhaps the most important message we must convey is that it is very expensive to cover the cost incurred by a patient who is dying from metastatic breast cancer. In fact, the total costs of dying from breast cancer are so high that there can be no true comparison between this cost and those that would have been incurred for yearly screening and, when the cancer was detected early, the cost of a mastectomy or lumpectomy.

The enclosed report shows the hospital costs of some of my patients who have recently died from metastatic breast cancer. It is important for you to realize that these figures do not include the cost of the mastectomy which was done elsewhere. These figures represent only the cost involved in providing hospital care for these patients as they waited to die.

It is equally important to realize that these figures do not include the oncologist's fee which customary range from **$1,700 to $2,000,** nor do they reflect the primary care physician's fees which can easily reach **in excess of $1,000.** Other physician fees such as interpretation fees, consulting fees and so forth are not included in these figures either.

Another important consideration are those costs that a woman incurs for various "treatments" which are normally prescribed for advanced disease or recurrent disease. These treatments include chemotherapy and radiotherapy. A two year course of **chemotherapy will average $9,600.** Each course of **radiotherapy is about $5,000;** and women may require several courses of this treatment as the cancer spreads to the brain, spine, hip, chest or to any other area of the body.

Among other "hidden" charges incurred by the woman dying from breast cancer are medications, rehabilitative or physical therapy treatments and home nursing care. The purchase of a **"good" prothesis is close to $300.**

In other words, these figures in this report reflect what **it costs to go into a hospital and die once** breast cancer has spread past the treatable stage.

Of course, we could never put a dollar amount on the emotional costs of breast cancer. For many women, this devastating disease has meant more than the loss of a breast and her health, but also includes the loss of husbands, family, friends, and most importantly, any feelings of self worth. It is a sad fact that for some women breast cancer has meant the loss of their jobs, and the associated financial security and medical benefits.

If we were to take the very "lowest" figure from my report and added even a portion of all the other costs I've presented, the most conservative total would be a fraction of what it would have cost to screen that same woman on an annual basis and to have treated her cancer at an earlier, and therefore, curable stage. **Most importantly, if this woman wouid have been screened and treated, we would not be discussing a woman who has died from breast cancer!**

It should be obvious that the costs of annual screening, and a curative mastectomy, are substantially lower than the ultimate costs involved in caring for a patient when the cancer has moved to a more advanced stage.

When I talk about "what it costs to go into a hospital and die," it's important to understand that at this stage of treatment there is nothing we can do but attempt to make the patient more comfortable, or take those measures which ward off immediate death.

A death from breast cancer is unlike dying from any other disease--even most other cancers. Usually hospital care is confined to inserting tubes to drain off fluid from the lungs to keep the woman from drowning -- a situation that can occur repeatedly during the last stages. Hospital care may include setting broken bones and trying to provide time for healing--which seldom happens. or providing custodial care when it reaches the brain or spine rendering the patient becomes totally helpless.

When you review the figures and number of hospital stays, bear in mind that several stays may represent only a two or three day period of hospitalization while we take those steps described. In the final days, when most of the expense is incurred, we are not "treating" this patient, we are simply waiting for death.

To truly understand the importance of mammography would require being with only one patient during that waiting period, listening to her drown on her own fluids and seeing her agony in every attempt to move her body -- all the time knowing that there is nothing that can be done and also realizing that this woman had, at one time, a chance for a 95% total recovery.

Thank you for your time and consideration.

Dixie Melillo M.D.

Dixie Melillo, M.D.
General Surgeon

HOSPITAL CHARGES FOR BREAST CANCER PATIENTS

Does not include cost of mastectomy, physician fees, medication, chemotheratherapy or radiotherapy.

(Due to patient confidentially, I have protected the identity of my patients in this report. However, I can verify that these figures are accurate and reflect true hospital stays. Should you require additional information concerning any or all of these patients, I would be glad to contact their families for release of such information. D. Melillo, M.D.)

PATIENT:	HOSPITAL CHARGES
Patient #1, EA First admission date: 10-31-84 Last admission date: 3-26-86 Total number of admissions: 7	$52,257
Patient # 2, A.J. First admission date: 8-25-85 Last admission date: 4.16-86 Total number of admissions: 7	$36,886
Patient #3, O.L. First admission date: 3-20-85 Last admission date: 9-7-86 Total number of admissions: 5	$29,821
Patient #4, D.K. First admission date: 4-5-85 Last admission date: 1-6-86 Total number of admissions: 4	$21,433
Patient # 5, R.P. First admission date: 6-27-85 Last admission date: 6-3-86 Total number of admissions: 4	$16,285

PATIENT:	**HOSPITAL CHARGES**
Patient #6, C.J. First admission date: 7-3-86 Last admission date: 11-20-87 Total number of admissions: 7	**$59,840**
Patient # 7, V.F. First admission date: 7-84 Last admission date: 6-87 Total number of admissions: 10	**$51,485**
Patient #8, F.M. First admission date: 5-86 Last admission date: Total Number of admissions: 7	**$17,836**

Patient #8, is a forty year old woman who is currently receiving care. During the last eighteen months she has already been through seven hospital admissions, and has received almost $10,000 worth of radiotherapy, ***bringing her basic cost of care thus far to $27,000.***

DIXIE MELILLO, M.D
General Surgeon, Private Practice
Pasadena, Texas
Board Certified, American College of Surgeons
Fellow, American College of Surgeons

Medical Training/Licensure:

Internship and Residency at the University of Texas Medical Branch, Galveston, Texas.
M.D. License in 1978, followed by a five year residency in surgery.

Professional Accomplishments:

Founder of THE ROSE, a non-profit organization for breast cancer screening.
Appointed Field Medical Liaison, Cancer Care Program by the American College of Surgeons
Chairperson of the Southeast Harris County Task Force, Texas Breast Cancer Screening Project, American Cancer Society, 1986, 1987, and 1988.
Selected as one of the **Top Ten "Women on the Move in Houston,"** 1985.

Professional appointments/Memberships:

Elected Alternate Delegate to the Texas Medical Association.
Appointed to the Texas Medical Association Council of Communications.
Member American Medical Association.
Member Southeast Harris County Medical Society.
1985, Co-Medical Director, Bayshore Breast Imaging Center,
  Pasadena Bayshore Medical Center.
1986, Chairman, Department of Surgery, Pasadena Bayshore Medical Center.
1987, Co-Chairman, Cancer Care Committee, Pasadena Bayshore Medical Center.

Civic Appointments:

Since 1985, member of the Board of Directors, Texas Commerce Bank, Pasadena Branch.
Since 1986, Chairman, Pasadena Chamber of Commerce, Medical Services Committee.

As a matter of information, at the time Dr. Melillo finished her Residency in 1983, only two other women had successfully completed the surgical residency program offered by UTMB. Additionally, at that time, in the United States, only 9% of all physicians were women, of that number less than 1% specialized in surgery.

Senator **Mikulski**. Doctor, that was very eloquent testimony as was that of the other physicians. I think you have put a human face on the numbers, and I think we are all kind of taken aback by it.

We now want to move to some questions.

Senator Adams, would you like to begin?

Senator **Adams**. I'll just ask one question, which concerns me. Your very graphic slides do make a tremendous impact.

What I want to hear from you is how we help to overcome this radiation fear. Both Senator Mikulski and I are in agreement on trying to get a funding mechanism in place. We understand that problem, also.

But generally throughout the people that we talk with, there is this radiation fear. Now, how do we best approach that—any of the panelists.

Dr. **Strax**. That is a very excellent question and something that has dogged us since 1977 when this commotion first began, that perhaps mammography could hurt.

Many important authorities--physicians and physicists—have looked into the matter from various angles, and the conclusion has been that there is no risk in women over the age of 35, if any even below that, but certainly over 35, there is no risk; and that the radiation that is being used today could not possibly hurt anyone, even if they were examined for 500 years, even on a periodic basis.

Now, this information needs to be more spread out in the media. It needs to be made more common to the average woman. You have got to overcome this terrible, terrible commotion that developed in 1977, which was unkind, unfair, and has led to the death of many women who did not get their examinations.

Senator **Adams**. That is my only question. Thank you.

Senator **Mikulski**. Senator Adams, maybe I can help you, as someone who has had a mammogram herself. First, when my physician suggested I have one, I didn't feel particularly ill or uncomfortable and wondered why. He explained that it was time for me to start to map my body. This was when I was at age 48.

I said, "What is a mammorgram?" And my immediate impression of it would be going to a radiologist's office and essentially having the equivalent of an airbag go off in front of you. And it wasn't so much that I feared radiation as it was that some balloon-like thing would give a smothering feeling, and I did not feel I needed it.

Fortunately, an aggressive and fine physician affiliated with Johns Hopkins encouraged me to overcome that reluctance. I was surprised to find out what a benign experience it was. It is a lot more uncomfortable riding the Senate elevator or taking the subway to Dirksen than undergoing a mammogram. And I think if there were either little videos that women could see, if there were public service announcements, because you think it will be something quite overwhelming, because you know it is going to be like an airbag-type experience; you think it is going to hurt; you think it is going to be heavy; you think it is going to be suffocating, and you also think you are going to get a nuclear zap, a radioactive zap. And I think some public education through videos and so on does that. I can tell anyone listening it is no more uncomfortable than any other x-ray you will take. It does not hurt. It certanly didn't hurt me.

And I am glad that right now, sitting in my doctor's office, there is a little map of Senator Mikulski.

Dr. STRAX. Thank you very much. I think that is wonderful. That kind of talk is what we need to go across the country.

Dr. MELILLO. Senator, may I add one thing?

Senator MIKULSKI. Yes.

Dr. MELILLO. When I give a talk to the community, I give out some statistics that—some little statistician someplace sat and figured this up—that if indeed doing the mammogram caused one excess death per million in the population screened, it would be equivalent to the risks of smoking three-fourths of one cigarette; travelling 400 miles by air; one of the really interesting ones is living for 20 minutes as a man age 60, the same risk.

So it kind of helps put it in a perspective that women understand that really, the risk is absolutely negligible.

Senator MIKULSKI. Well, I'd like to ask that, Dr. Strax, because I think there is that concern, as you said, because of some of the unsavory testimony. Are there any risks associated with having a mammography, and what would be the level of the risk?

Dr. STRAX. There is no risk associated with a mammogram. The commotion developed over the concept that if we were going to do periodic mammograms and were going to examine a woman, let us say, at the age of 40 and do it every year for 20 or 30 years, perhaps enough radiation would have accumulated to cause trouble at that time. Nobody in his right mind has ever said that a mammogram could have caused any harm whatsoever to a woman.

Senator MIKULSKI. Thank you.

My last question goes to Dr. Smart. And again, I congratulate the National Cancer Institute on the wonderful job it is doing over there at NIH.

You have a goal of reducing mortality from cancer by the year 2000 by 50 percent. How do you hope to do that in the area of breast cancer, Dr. Smart?

Dr. SMART. Well, we have just met recently with all of the medical organizations and had them as consultants to us to see if we could develop a uniform recommendation regarding mammography, and as a result of this meeting, we have reduced the age at which we would begin mammography. On September 30th the National Cancer Advisory Board approved this recommendation. Mammography should begin at the age of 40, and it should then be every one to two years, and after the age of 50, it probably ought to be annual.

I would say that if this were carried out, and if the results of the BCDDP, the breast cancer demonstration project that was funded by the National Cancer Institute and the American Cancer Society—after all, there were nearly a quarter of a million women who were screened across this country. They have now been followed up for ten years. And if we were able to take the results that came from them and to have it be representative of what we might do in the country as a whole, the mortality rate would now be decreased by 46 percent if you looked at the survival rate of those women in that quarter of a million women who were screened.

So we believe that the bill and the recommendations you are coming forth with are specifically reasonable recommendations, and that if we can in any way encourage women to get a mammogram, because it is at reasonable cost, and because we can overcome this fear of radiation risk, and through working through all the medical associations and getting all doctors, also, fully committed to that goal, we think that is how we can achieve the goal.

Senator **Mikulski**. I think that is excellent. I am going to ask you to do one more thing, which is to do some consciousness-raising with the Health Care Financing Administration to get behind us. Here, you have one arm of the United States Government doing wonderful research in the area of cancer detection and cancer treatment, and obviously developing an important public health education component. But maybe some education out there at Woodlawn and down here on Independence Avenue would help a lot.

We thank the witnesses for their testimony and for being so dedicated in this field.

Thank you.

We now want to move on to Part 2 of our hearing.

Senator Adams?

Senator **Adams**. We want to give everybody an opportunity to have shifted, although we are on the same subject. I want to welcome all of you here today again.

I explained earlier the reason that I was not here at the opening of the hearing, and I want to thank Senator Mikulski for starting. I was at the INF hearings, and it is difficult to do both. But I consider this of incredible importance.

My mother died of lung cancer; it was undetected for a long period of time. My wife has been fortunate enough to have followed through on a program, and we are going to hear this morning from witnesses as to why that was so terribly important.

I have daughters, and the women in my family deserve a chance and deserve better than what has happened in the past. I think Senator Mikulski put it very well in her statement, that many women have been fearful, have found this, they believe, to be intrusive. But this is a matter, as we are hearing this morning, of life and death, and of whole lives of people.

I am particularly grateful that Barbara Arbuckle and Lea Thompson will be here on the first panel this morning. We are going to discuss now Pap smears, and one of the things we want to focus on—and I hope all of you in the room have had an opportunity to see some of the things that have been done by the press. And I want to express my gratitude to them for having done this, of showing in local areas, and I hope it will move to national areas, what we are concerned about with Pap smears.

Here, we have a program that can detect cervical cancer. It is a known technique, but we have found a fantastic error rate. The false "positive" to "negative" rate is just unbelievable. And we are going to have personal testimony from witnesses this morning of their experiences. And I am grateful to them that they will share them so that all women can understand and personalize this experience.

We will also have statistical evidence this morning that shows that we are not regulating laboratories and that the medical profession has a long way to go in determining that the smears are properly taken.

I am appalled by the fact that we have visual examination of Pap smears in laboratories, and that this technique is dependent obviously upon first, an excellent sample being taken, and second, that the examination is not done by somebody so tired after having done 80 or more that we should set Federal standards as to how many examinations.

I am going to let the witnesses say this, but I want you to know that we have followed this, and that it is one reason that Senator Mikulski and I are so appalled by it. If we have a false "positive" to "negative" rating that traps people, then our program immediately collapses on itself. And we want to know from the panels this morning the types of regulation—and we are not regulating for regulation's sake. We just simply want the people who are examining in these Federal laboratories to be alert and able to do this.

And I think to put it into an economic market situation where you are paying on a piecework basis and having people go from laboratory to laboratory and become so tired that their error rate becomes so high that the whole program is endangered is something we have to move on. We want women to do this. We also want women to have confidence in the program. That is what this is all about when we are talking now about Pap smears and cervical cancer.

I appreciate, Ms. Arbuckle, your coming this morning. Welcome. You are from my home city. We are proud of our home city and the fact that people will speak out, and I am grateful to you for that. I know it is difficult for you, and I appreciate it. I personally appreciate it, and your country appreciates it.

And Lea, we are very much looking forward to the results of your examination. I have found, and I know Senator Mikulski has found, that we have to personalize things in this government very often in order to make things happen. We drown in statistics. I want to hear those; I want the witnesses to testify about them; I find them appalling. But the personalization is important.

So we welcome Ms. Arbuckle and Ms. Thompson as the first panel, and whichever of you would like to proceed first.

Lea, why don't you start? Welcome.

Senator MIKULSKI. Lea, before you do, I want everyone to know that it is the results of your investigation on Channel 4, called "Deadly Mistakes" that really moved me to become involved in this issue. We want to congratulate you on behalf of the first-rate journalism that you did. We look forward to your testimony in that behalf.

As women, you and I know that confronting cancer is a terror. Having a cervical examination is not a jolly experience. But then, after we go through having a Pap smear, to find out that we not only have to fear the disease, we now have to fear the test for the disease, is indeed a fatal situation.

So we look forward to hearing from you. And Senator Adams, I know you are fresh from the INF Treaty. I think what the women of America want is the same thing we want in our verification treaty—we want something that is achievable, reliable and enforceable.

Senator ADAMS. Well-put; excellent.

Ms. Thompson?

STATEMENTS OF LEA THOMPSON, INVESTIGATIVE REPORTER, CONSUMER AFFAIRS UNIT, WRC-TV NEWS 4, WASHINGTON, DC; AND BARBARA ARBUCKLE, SEATTLE, WA

Ms. THOMPSON. Thank you, Senator Adams, Senator Mikulski. I am indeed happy to have been asked to bring you the results of our investigation this morning.

In particular, of course, we have been asked to deliver what we discovered about Pap smears. We called our series of special reports "Deadly Mistakes". It appeared first on Channel 4 here in Washington as a five-part series, later as "Today Show" piece, and even later than that as a half-hour documentary. We thought it was that important.

As you will see, the term "Deadly Mistakes" was used, we believe, with good reason.

Our investigation involved weeks of courthouse checks, freedom of information requests, days of reviewing documents, medical records, Medicare inspection reports, State inspection reports. We traveled to nine States from Florida to New York, so we do believe that we can bring you the results of an investigation that we are proud of.

Among our findings, in half of the States in this country, nobody inspects or regulates non-Medicare laboratories at all.

In the Washington Metropolitan Area, about one-third of the commercial labs in Virginia are never inspected or regulated because of a huge hole in that State's law.

In Maryland and the District of Columbia, nearly half the medical labs could not prove that they performed quality control procedures or tested equipment for accuracy.

Throughout the area, we found tens of thousands of private doctors' laboratories—some that do Pap smears, by the way—only 80 of those have been inspected in the Washington area.

And we found many people doing very sophisticated tests—of course, Pap smears are very sophisticated—with almost no training.

The most shocking problem we found, however, was indeed Pap smears.

As you are well aware, as you spoke eloquently about, a labor report is very critical to a diagnosis like cancer, and a lab report really can mean the difference between life and death.

Since I am a broadcast journalist, I think the best way to tell you about what we discovered is to show you a compilation of our stories that dealt specifically with the Pap smear issue.

Before I begin my video presentation, I do want to introduce you to our team at Channel 4. Obviously, I did not do this alone.

Please meet our investigative producer, Rick Nelson; our chief researcher, Sheila Duffy; our news director, Brett Marcus, also joins me this morning.

And if you would, please take a look at the television screen. What you are about to see was also edited by John Spillane.

So, could we roll the tape?

[Videotape shown. Complete text follows:]

TESTIMONY OF LEA THOMPSON, REPORTER
WRC-TV NEWS, WASHINGTON, D.C.
BEFORE THE U.S. SENATE
COMMITTEE LABOR AND HUMAN RESOURCES COMMITTEE
JANUARY 28, 1988

GOOD MORNING MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE. I AM PLEASED TO HAVE BEEN ASKED THIS MORNING TO BRING YOU THE FINDINGS OF OUR FOUR MONTH INVESTIGATION ON MEDICAL LABORATORIES AND, IN PARTICULAR, WHAT WE DISCOVERED ABOUT PAP SMEARS. WE CALLED OUR SERIES OF SPECIAL REPORTS AND LATER "TODAY SHOW" STORY AND HALF HOUR DOCUMENTARY "DEADLY MISTAKES." AS YOU WILL SEE, IT IS WITH GOOD REASON.

OUR INVESTIGATION REQUIRED WEEKS OF COURTHOUSE CHECKS, FREEDOM OF INFORMATION REQUESTS, AND DAYS OF REVIEWING DOCUMENTS, MEDICAL RECORDS, MEDICARE AND STATE INSPECTION REPORTS AND LAB REPORTS. WE TRAVELED TO NINE STATES FROM FLORIDA TO NEW YORK.

AMONG OUR FINDINGS:

- IN HALF THE STATES IN THIS COUNTRY NO ONE INSPECTS OR REGULATES NON-MEDICARE LABS AT ALL.

- IN THE WASHINGTON METROPOLITAN AREA, ABOUT ONE THIRD OF THE COMMERCIAL LABS IN VIRGINIA ARE NEVER INSPECTED OR REGULATED BECAUSE OF A HUGE HOLE IN THAT STATE'S LAW.

- IN MARYLAND AND THE DISTRICT OF COLUMBIA, NEARLY HALF THE MEDICAL LABS COULD NOT PROVE THEY PERFORMED QUALITY CONTROL PROCEDURES OR TESTED EQUIPMENT FOR ACCURACY.

- THROUGHOUT THE AREA THERE ARE TENS OF THOUSANDS OF PRIVATE DOCTORS LABORATORIES. ONLY EIGHTY HAVE BEEN INSPECTED. AND WE FOUND PEOPLE DOING SOPHISTICATED TESTS WITH ALMOST NO TRAINING.

- THE MOST SHOCKING PROBLEM WE FOUND WAS PAP SMEARS.

AS YOU ARE WELL AWARE, A LAB REPORT IS CRITICAL TO A DIAGNOSIS LIKE CANCER. AND A LAB REPORT CAN MEAN THE DIFFERENCE BETWEEN LIFE AND DEATH.

SINCE I AM A BROADCAST JOURNALIST, THE BEST WAY TO TELL YOU WHAT WE DISCOVERED IS TO SHOW YOU A COMPILATION OF OUR STORIES THAT DEALT SPECIFICALLY WITH THE PAP SMEAR ISSUE.

BEFORE I BEGIN THE VIDEO PRESENTATION I WOULD FIRST LIKE TO INTRODUCE YOU TO OUR TEAM THAT PRODUCED THIS INVESTIGATION. INVESTIGATIVE PRODUCER RICK NELSON AND RESEARCHER SHEILA DUFFY. ALSO JOINING ME THIS MORNING, OUR GENERAL MANAGER ALLAN HORLICK, OUR NEWS DIRECTOR BRET MARCUS AND OUR ATTORNEY MOLLY PAUKER.

IF WOULD PLEASE TURN YOUR ATTENTION TO THE TELEVISION SCREEN. WHAT YOU ARE ABOUT TO SEE WAS EDITED BY JOHN SPILLANE.

PLEASE ROLL THE TAPE.

**********************************BEGIN TAPE**********************************

JANET COLEMAN (VICTIM):
"IT'S THE LABORATORY'S FAULT THAT I'M IN THE SHAPE I'M IN."

JOANNE JONES (VICTIM):
"THEY'RE SUPPOSED TO BE TRAINED TECHNICIANS AND THAT'S WHAT THEY'RE THERE FOR. TO FIND THESE PROBLEMS THAT PEOPLE HAVE."

ALEXANDRA SLOAN (VICTIM):
"YOU NEVER THINK THIS IS GOING TO HAPPEN IN REAL LIFE."

THOMPSON:
MOST PEOPLE ARE CAREFUL ABOUT PICKING A DOCTOR BUT HAVE YOU EVER QUESTIONED WHERE YOUR LAB WORK IS BEING DONE AND WHO IS DOING IT? DURING NEWS FOUR'S FIVE MONTH INVESTIGATION INTO MEDICAL LABS WE FOUND AN ALARMING NUMBER OF MISTAKES, FAR TOO OFTEN, DEADLY MISTAKES.

ANNOUNCER:
DEADLY MISTAKES. A NEWS FOUR SPECIAL REPORT WITH LEA THOMPSON.

THOMPSON:
AMERICANS SPENT UP TO 150 BILLION DOLLARS LAST YEAR ON MEDICAL TESTS, AN AVERAGE TWENTY TESTS FOR EVERY MAN, WOMAN AND CHILD IN THIS COUNTRY. MEDICAL LABORATORIES ANALYZE EVERYTHING FROM BLOOD AND URINE TO CHOLESTEROL AND CANCER. THEY HELP YOUR DOCTOR DECIDE IF YOU ARE WELL OR SICK.

THERE ARE THOUSANDS OF HOSPITAL, COMMERICAL AND DOCTORS OFFICE LABS IN THE WASHINGTON AREA. MOST DO A GOOD JOB BUT WE FOUND TOO MANY CASES OF CARELESSNESSNESS OR NEGLECT, TOO MANY PATIENTS WHO HAD UNNECESSARY SURGERY OR CHEMOTHERAPY, TOO MANY PEOPLE WHO HAVE DIED BECAUSE A LAB MESSED UP.

WE FOUND LARGE NUMBERS OF UNTRAINED TECHNICIANS WORKING IN THOUSANDS OF LABS THAT ARE NEVER INSPECTED OR TESTED FOR ACCURACY IN OUR REGION. AND A REGULATORY SYSTEM THAT IS SPOTTY AT BEST, SOMETIMES NONEXISTENT.

IRONICALLY, THE MOST SERIOUS SPECIFIC PROBLEM WE FOUND WAS WITH A COMMON TEST THAT WOMEN UNDERGO EVERY YEAR, THE PAP SMEAR.

JANET COLEMAN (VICTIM):
"THERE'S NOTHING I CAN DO NOW. I FEEL TOTALLY USELESS."

THOMPSON:
JANET COLEMAN WENT TO HER DOCTOR FOR A PAP SMEAR. THE LAB REPORTED THERE WAS NO PROBLEM. BUT SHE KNEW SOMETHING WAS WRONG.

JANET COLEMAN (VICTIM):
"I KEPT GETTING WORSE I DIDN'T GET ANY BETTER."

THOMPSON:
WHEN JANET RETURNED TO HER DOCTOR EIGHT MONTHS LATER IT WAS CANCER. HE ASKED THE LAB TO GO BACK AND DOUBLE CHECK THE ORIGINAL PAP SMEAR SLIDE. THE CANCER HAD BEEN THERE ALL ALONG. IN THAT EIGHT MONTHS HER CERVICAL CANCER HAD BECOME TOO ADVANCED FOR SURGERY.

JANET COLEMAN (VICTIM):
"MOMMY LOVES YOU. DO YOU LOVE ME? MAYBE GOD WILL SEE FIT TO SPARE ME, GIVE ME TIME, ESPECIALLY TO RAISE MY LITTLE GIRL UP SO SHE CAN TAKE CARE OF HERSELF BETTER."

THOMPSON:
SIXTY THOUSAND WOMEN WILL DEVELOP CANCER OF THE CERVIX THIS YEAR. IT IS 90% CURABLE IF IT IS CAUGHT EARLY. HOWEVER, SEVEN THOUSAND WOMEN DO DIE OF IT

EVERY YEAR. FOR SOME IT IS BECAUSE THEY NEVER GOT A PAP SMEAR, FOR OTHERS IT IS THE RESULT OF A DEADLY MISTAKE.

NEW YORK TECHNOLOGIST:
"YOU REALLY HAVE TO CONCENTRATE ON WHAT YOU'RE DOING."

THOMPSON:
PAP SMEAR SLIDES ARE REVIEWED BY TECHNOLOGISTS. IT IS TEDIOUS WORK, LOOKING AT SLIDE AFTER SLIDE, HOUR AFTER HOUR.

NEW YORK TECHNOLOGIST:
"AFTER TWO HOURS OF LOOKING IN THE SCOPE YOUR EYES CAN GO BATTY."

THOMPSON:
THIS IS WHAT THEY SEE. ABNORMAL CELLS ARE EASY TO MISS. IN FACT, SOME JUST WENT BY. THESE ARE NORMAL CELLS, THESE ARE CANCER CELLS, AND THESE ARE IN BETWEEN. BY SPOTTING THAT ABNORMAL CELL, A TECHNOLOGIST CAN SAVE A LIFE. A MISTAKE CAN BE FATAL. EVEN KNOWING THAT, SOME LABS FORCE TECHNOLOGISTS TO REVIEW TOO MANY SLIDES TOO FAST.

JANET COLEMAN'S PAP SMEAR WAS REVIEWED BY NATIONAL HEALTH LABS IN VIENNA VIRGINIA, A LARGE LAB THAT REVIEWS A QUARTER MILLION PAP SMEARS A YEAR FROM AS FAR AWAY AS CLEVELAND AND ATLANTA.

THOMPSON:
FROM READING THIS REPORT, IT WOULD APPEAR THE LAB'S MEDICAL DIRECTOR, DOCTOR DAN FERIOZI, HAD PERSONALLY REVIEWED JANET COLEMAN'S CASE. BUT HE NEVER SAW IT. THE LAB JUST STAMPS HIS NAME ON THE REPORTS. AS FOR JANET COLEMAN, HER SLIDE WAS SCREENED BY A PART-TIME EMPLOYEE WHO WAS FILLING IN ON THE NIGHT SHIFT.

(REVLON COMMERCIAL)
"REVLON WOMEN DARE TO GET THIS CLOSE."

THOMPSON:
THE LAB IS PART OF A HUGE NATIONWIDE CHAIN OWNED BY REVLON. WHILE LAB OFFICIALS WOULDN'T TALK TO US WE DID OBTAIN INTERNAL DOCUMENTS THAT SHOW TECHNOLOGISTS ARE REQUIRED TO READ ONE HUNDRED TWENTY PAP SMEAR SLIDES A DAY IN ORDER TO GET FULL PAY. THAT IS TWO TO THREE TIMES THE RECOMMENDED LIMIT FOR ACCURACY. EXPERTS SAY THAT IS DANGEROUS.

DR. HERB DICKERMAN (WADSWORTH CENTER, N.Y. HEALTH DEPT.):
"THE BOTTOM LINE IS THE CARE OF THE PATIENT."

THOMPSON:
DR. HERB DICKERMAN IS HEAD OF THE NEW YORK STATE HEALTH DEPARTMENT WHICH HAS THE BEST INSPECTION PROGRAM IN THE COUNTRY.

THOMPSON:
"WHAT ABOUT A LAB THAT REQUIRES ITS TECHNOLOGISTS TO READ 120 SLIDES A DAY? DOES THAT SEND UP A FLAG FOR YOU?"

DR. HERB DICKERMAN (WADSWORTH CENTER, N.Y. HEALTH DEPT.):
"IT SENDS UP A BIG FLAG FOR ME. IT SENDS UP A FLAG THAT THE PERSON IS NOT AS INTERESTED IN THE QUALITY OF THE INTERPRETATION AS IN PRODUCTION. AND THAT'S ALWAYS DANGEROUS IN LABORATORY MEDICINE."

THOMPSON:
THIS NEW YORK HEALTH DEPARTMENT TECHNOLOGIST DOES AVERAGE TEN TO TWELVE MINUTES TO REVIEW A PAP SMEAR. THAT'S ONLY 35 TO 40 SLIDES A DAY. WE ASKED HER TO DEMONSTRATE HOW SHE WOULD HAVE TO DO IT IN 4 MINUTES.

TECHNOLOGIST:
"THIS STUFF IS JUST FLYING BY. I DON'T THINK I COULD DO A GOOD JOB DOING IT LIKE THIS. I WOULDN'T BE FAIR TO THE PATIENT AT ALL."

DR. DECLAN BURKE (CULPEPPER, VA. PHYSICIAN):
"THEY SEEM NOT TO GIVE A DAMN."

THOMPSON:
DR. DECLAN BURKE OF CULPEPER VIRGINIA WAS JANET COLEMAN'S DOCTOR. AFTER HER ERROR WAS DISCOVERED, HE ASKED THE NATONAL HEALTH LABS TO DOUBLE CHECK PAP SMEARS FOR HIS OTHER PATIENTS.

DR. DECLAN BURKE (CULPEPPER, VA. PHYSICIAN):
"NONE OF THE PHYSICIANS I WROTE TO EVER RETURNED MY LETTERS. I HAD ONE REPLY FROM ONE NON-PHYSICIAN TYPE WHO SAID THEY WEREN'T GOING TO REVIEW ANYTHING."

THOMPSON:
BUT NATIONAL HEALTH LABS IS NOT THE ONLY PLACE THAT MAKES MISTAKES AND WHERE PEOPLE WORK TOO FAST.

BOB JOHNSON (WIDOWER): —
"THEY MIGHT AS WELL AS PUT A GUN TO HER HEAD AND KILLED HER."

THOMPSON:
BOB JOHNSON'S WIFE JANICE, A MOTHER OF TWO YOUNG CHILDREN, HAD HER PAP SMEARS REVIEWED BY A WOMAN WHO ADMITS SHE SOMETIMES SCREENED THREE HUNDRED SLIDES A DAY AT NORTHERN VIRGINIA DOCTOR'S HOSPITAL. THAT'S FOUR TO FIVE TIMES THE RECOMMENDATION FOR ACCURACY. JANICE JOHNSON DIED AT AGE THIRTY-FIVE.

BOB JOHNSON (WIDOWER):
"IT CAN BE PROVEN THAT THEY MISSED IT TWICE. MY CONTENTION IS, AND IT WAS JAN'S, THAT THEY MISSED IT THREE, FOUR, FIVE TIMES."

THOMPSON:
SANDRA MAGRUDER'S DOCTOR IN THE DISTRICT SENT HER PAP SMEARS TO A MAIL ORDER LAB IN CALIFORNIA THAT ADVERTISED LOW PRICES AND QUICK SERVICE. THE LAB MISREAD HER PAP SMEARS TWICE IN NINE MONTHS. AND THEN MEDICAL EXPERTS SAY METPATH IN KENSINGTON GOT A BIOPSY WRONG. SANDRA MAGRUDER DIED AT AGE 36.

ERIKA HEDEN'S LABORATORY FAILED TO DIAGNOSE THE SERIOUSNESS OF HER CANCER. SHE DIED AT AGE 28.

JOANNE JONES:
"IT BOTHERS ME ALOT TO KNOW I CAN'T HAVE KIDS."

THOMPSON:
THE LABORATORY MISREAD JOANNE JONES' PAP SMEAR. BY THE TIME THE CANCER WAS FOUND SHE HAD TO HAVE A HYSTERECTOMY AT AGE 22.

EVERYWHERE WE LOOKED WE FOUND MORE PROBLEMS WITH PAP SMEARS THAN ANYTHING ELSE YET ONLY ONE STATE BOTHERS TO TEST THE ACCURACY OF TECHNOLOGISTS WHO READ PAP SMEARS. IT ONLY HAPPENS HERE IN ALBANY, THE CAPITAL OF NEW YORK.

AND NEW YORK'S TEST RESULTS ARE VERY DISTURBING. TWENTY PERCENT OF THE LABS FLUNKED THE LATEST EXAMS, EVEN THOUGH THEY KNEW THEY WERE BEING TESTED. THAT'S BETTER THAN THE 47 PERCENT THAT FLUNKED WHEN NEW YORK STARTED THE INSPECTION PROGRAM BUT IT CERTAINLY MAKES YOU WONDER HOW LABS IN EVERY OTHER STATE MIGHT DO.

THE HEAD OF MARYLAND'S INSPECTION PROGRAM SAYS TESTING PAP SMEAR TECHNOLOGISTS IS TOO EXPENSIVE. DR. JACK DeBOY.

DR. JACK DEBOY (MARYLAND HEALTH DEPT.):
"IT IS EXTREMEMLY DIFFICULT TO COME UP WITH A PROFICIENCY TEST OF THIS TYPE. DIFFICULT, TIME CONSUMING AND A COSTLY TYPE PROGRAM."

DR. HERB DICKERMAN (WADSWORTH CENTER, N.Y. HEALTH DEPT.):

"YOU CAN'T LOOK AT IT IN TERMS OF DOLLARS AND CENTS. WHAT'S MORE EXPENSIVE? A WOMAN WHO DIES UNNECESSARILY OR THE COST OF A PROGRAM."

THOMPSON:
TO ENSURE ACCURACY, LAB EQUIPMENT MUST BE REGULARLY INSPECTED AND CHEMICALS TESTED FOR POTENCY. IT'S CALLED QUALITY CONTROL. QUALITY CONTROL CAN BE COMPARED TO AN AIRLINE PILOT'S CHECKLIST. IT'S THE ONLY WAY TO VERIFY EVERYTHING IS WORKING ACCURATELY.

DR. DAVID WILKINSON (GEORGE WASHINGTON UNIVERSITY HOSPITAL):
"IF QUALITY CONTROL IS POOR THEN YOU CANNOT RELY ON THE RESULTS."

THOMPSON:
QUALITY CONTROL IS A COMMON PROBLEM. MEDICARE INSPECTION REPORTS SHOW THAT IN MARYLAND, FORTY THREE PERCENT OF THE LABS COULD NOT DOCUMENT THEY REGULARLY INSPECTED EQUIPMENT AND MATERIALS FOR ACCURACY. IN THE DISTRICT, 42 PERCENT, VIRGINIA 27 PERCENT.

JOSEPHINE BARTOLO (PENNSYLVANIA HEALTH DEPT.):
"THE FEDERAL GOVERNMENT HAS NEGLECTED A LARGE PORTION OF THE LABORATORY COMMUNITY."

SENATOR WILLIAM S. COHEN (R/MAINE):
"WE ARE SPENDING $1.6 BILLION IN MEDICARE PAYMENTS FOR LAB TESTS WITH VIRTUALLY NO GUIDELINES OR SUPERVISION."

THOMPSON:
AT AT TIME WHEN MANY BELIEVE THE FEDERAL GOVERNMENT SHOULD BE DOING FAR MORE TO ENSURE ACCURACY AND PRECISION IN LABORATORIES, THE GOVERNMENT IS DOING FAR LESS.

JUST SOME EXAMPLES. TWO YEARS AGO, THE CENTERS FOR DISEASE CONTROL STOPPED TESTING INTERSTATE LABS FOR ACCURACY. NOW THEY ARE TESTED BY INDUSTRY ASSOCIATIONS THAT THE LABS HIRE THEMSELVES. THE LABS KNOW WHEN THEY ARE BEING TESTED AND PUT THEIR BEST PEOPLE ON AN EXAM.

CONGRESSMAN RON WYDEN (D/OREGON):
"THE CURRENT SELF POLICING SYSTEM IS NOT WORKING."

THOMPSON:
AND JUST A FEW MONTHS AGO THE GOVERNMENT DECIDED TO MAKE IT EVEN EASIER. TO PASS BLOOD WORK AND CHEMISTRY TESTS, LABS NOW ONLY NEED A SEVENTY.

SENATOR WILLIAM S. COHEN (R/MAINE):
"IN HIGH SCHOOL 70 WAS A D-."

JANET COLEMAN (VICTIM):
"SOMETIMES I GET SO DEPRESSED AND DOWN I WISH IT WOULD BE SOON AND BE OVER WITH."

THOMPSON:
ON NOVEMBER 14TH JANET COLEMAN DIED AT THE UNIVERSITY OF VIRGINIA HOSPITAL IN CHARLOTTESVILLE.

LISTEN TO JANET COLEMAN. SHE HAS PAID WITH HER LIFE FOR SOMEONE ELSE'S MISTAKE.

JANET COLEMAN (VICTIM):
"MY DOCTOR SAID I WOULD'VE STOOD A VERY GOOD CHANCE OF LIVING. EVIDENTLY THE PERSON DIDN'T KNOW WHAT HE WAS DOING. I WONDER HOW MANY OTHER WOMEN THIS HAS HAPPENED TO. I'D LIKE TO WARN OTHER WOMEN. GET A SECOND OPINION."

MR. CHAIRMAN, SOME CYTOTECHNOLOGISTS WORK ALL DAY AT ONE JOB AND WORK A SECOND SHIFT SOMEWHERE ELSE. MANY LABS PAY ON A PIECEMEAL BASIS AND SOME LABS EVEN ALLOW PEOPLE TO TAKE SLIDES HOME. IT IS HARD TO IMAGINE THAT THE WOMAN WHO LOOKED AT JANICE JOHNSON'S SLIDES SOMETIMES SCREENED THREE HUNDRED SLIDES A DAY.

PAP SMEARS ARE NOT EASY TO READ. HAVING SEEN CYTOTECHNOLOGISTS AT WORK, I HAVE ENORMOUS RESPECT FOR THEM. IT'S NOT A JOB THAT I COULD DO AND IT'S A JOB FEWER AND FEWER PEOPLE ARE WILLING TO DO. THE PAY IS SIMPLY TOO LOW TO ATTRACT PEOPLE TO THE FIELD. AS A RESULT, IT IS GETTING HARD TO FIND A TRAINED PERSON. MANY SCHOOLS FOR CYTOTECHS ARE CLOSING DOWN.

EVERYONE WE TALKED TO IN OUR AREA SAYS IT'S TOO EXPENSIVE AND TOO DIFFICULT TO MAKE SURE TECHNOLOGISTS KNOW WHAT THEY ARE DOING. DR. HERB DICKERMAN, WHO SPENT A GREAT DEAL OF HIS TIME HELPING US WITH OUR STORY, WILL TELL YOU THIS MORNING THAT JUST IS NOT TRUE.

I ANTICIPATE ONE OF THE QUESTIONS YOU MAY ASK IS WHETHER WE HAVE ANY ESTIMATES ABOUT HOW MANY MISTAKES ARE BEING MADE AND WHETHER THEIR ARE MORE PAP SMEAR MISTAKES THAN MISTAKES IN OTHER AREAS. OUR GUT REACTION IS THAT THERE ARE MORE PAP SMEAR MISTAKES, PRIMARILY BECAUSE THEY ARE SO PRONE TO DOCTOR ERROR IN TAKING THE SAMPLE AND TO TECHNICAL ERROR IN READING THAT SAMPLE.

WE FOUND MORE LAWSUITS INVOLVED PAP SMEARS THAN ANY OTHER TEST. WE BELIEVE THAT IS DUE TO THE FACT THAT IF A MISTAKE IS MADE ON A PAP SMEAR, YOU DIE. DEATHS AT A YOUNG AGE HAVE A WAY OF BECOMING LAWSUITS. A PAP SMEAR IS ONE OF THE FEW TESTS WHERE THE EVIDENCE IS KEPT AND THAT MAKES IT EASIER TO PROVE YOUR CASE.

MOST PEOPLE, MOST DOCTORS, TAKE LAB WORK FOR GRANTED. JUST LIKE IN THE CASE OF BARBARA ARBUCKLE, THE YOUNG WOMAN WHO WILL BE TESTIFYING NEXT, PEOPLE ASSUME LAB TESTS ARE RIGHT.

WE SUSPECT THEIR ARE MORE PAP SMEAR ERRORS THAN ANYBODY KNOWS. THE PEOPLE WE INTERVIEWED SAID THEY FOUND OUT ABOUT LAB ERRORS BY ACCIDENT. LETS FACE IT, IT IS NOT IN A LAB OR DOCTORS BEST INTEREST TO TALK ABOUT THEIR DEADLY MISTAKES.

"DEADLY MISTAKES" - FIVE PART SERIES, "TODAY SHOW" SEGMENT AND DOCUMENTARY
AIR DATES: (SERIES) NOVEMBER 16,17,18,19,20, 1987
(TODAY SHOW) DECEMBER 7, 1987
(DOCUMENTARY) DECEMBER 18, 1987

PRODUCERS/WRITERS: RICK NELSON, LEA THOMPSON
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(COPYWRITE: WRC-TV, NEWS 4 WASHINGTON)
"DEADLY MISTAKES" - PART I
NOVEMBER 16, 1987
WRC-TV NEWS
NEWS FOUR AT SIX

WRC-TV 4
WASHINGTON, D.C.

REPORTER: LEA THOMPSON
PRODUCER: RICK NELSON
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ANCHOR:

TONIGHT WE BEGIN A SERIES OF SPECIAL REPORTS ON MEDICAL LABORATORIES. LEA THOMPSON AND OUR INVESTIGATIVE UNIT HAVE JUST COMPLETED A FOUR MONTH STUDY THAT WE THINK IS ALARMING AND IMPORTANT. WE HOPE YOU WILL PUT DOWN WHAT YOU'RE DOING FOR THE NEXT EIGHT MINUTES BECAUSE THIS IS A TRADEGY THAT COULD HAPPEN TO YOU.

LEA THOMPSON:

WE ARE CALLING THIS SERIES OF SPECIAL REPORTS "DEADLY MISTAKES." AND, AS YOU WILL SEE, IT IS WITH GOOD REASON. THIS IS A TRADEGY THAT COULD HAPPEN TO YOU.

FULLY 10% OF YOUR MEDICAL BILL NOW GOES TO LAB WORK...DIAGNOSTIC TESTING. YOU'RE CAREFUL ABOUT HOW YOU PICK A DOCTOR. BUT HAVE YOU EVER QUESTIONED WHERE YOUR LAB WORK IS BEING DONE AND WHO'S DOING IT?

TONIGHT A LOOK AT ONE OF THE MOST COMMON TESTS DONE IN A LAB. THE PAP SMEAR. 60,000 WOMEN WILL DEVELOP CANCER OF THE CERVIX THIS YEAR. IT IS 90% CURABLE IF ITS CAUGHT EARLY. THAT IS WHY IT'S RECOMMENDED WOMEN HAVE A PAP SMEAR DONE ONCE A YEAR. BUT 7,000 WOMEN WILL DIE THIS YEAR OF CANCER OF THE CERVIX. FOR TOO MANY IT WILL HAVE BEEN A TRAGIC MISTAKE, A DEADLY MISTAKE BY A LAB.

(BEGIN VIDEO TAPE)••

JOANNE JONES (VICTIM):

"IT BOTHERS ME ALOT TO KNOW I CAN'T HAVE KIDS."

THOMPSON:

THE LABORATORY MISREAD JOANNE JONES' PAP SMEAR. BY THE TIME THE CANCER WAS FOUND SHE HAD TO HAVE A HYSTERECTOMY AT AGE 22.

JANET COLEMAN (VICTIM):

"I'M GONNA DIE BECAUSE OF THE LABORATORY."

THOMPSON:

A LAB ERROR ALLOWED JANET COLEMAN'S CANCER TO SPREAD FOR EIGHT MONTHS. NOW DOCTORS GIVE HER ONLY WEEKS TO LIVE.

BOB JOHNSON (WIDOWER):

"THEY MIGHT AS WELL AS HAD A GUN IN THEIR HANDS AND KILLED HER. (6)

THOMPSON:

BOB JOHNSON'S WIFE HAD CANCER. BUT A LAB MISSED IT NOT ONCE...BUT TWICE. BY THE TIME CANCER WAS DETECTED IT WAS TOO LATE. JANICE JOHNSON DIED AT AGE THIRTY SIX.

THESE WOMEN ARE VICTIMS. THEIR CASES ARE JUST A FEW OF THE DEADLY MISTAKES AND LAB ERRORS WE FOUND DURING OUR FOUR-MONTH INVESTIGATION OF MEDICAL LABORATORIES IN THE WASHINGTON AREA. WE REVIEWED HUNDREDS OF DOCUMENTS.

MEDICAL RECORDS, STUDIES AND COURT CASES AND TRAVELED UP AND DOWN THE EAST COAST TO GET THIS STORY. AMONG OUR FINDINGS:

- IN VIRGINIA, ABOUT ONE THIRD OF THE COMMERCIAL LABS ARE NEVER INSPECTED OR REGULATED BECAUSE OF A HUGE HOLE IN THE STATE'S LAW.

- IN MARYLAND AND THE DISTRICT OF COLUMBIA, NEARLY HALF THE MEDICAL LABS COULD NOT PROVE THEY PERFORMED QUALITY CONTROL PROCEDURES OR TESTED EQUIPMENT FOR ACCURACY.

THROUGHOUT THE AREA THERE ARE 28,000 PRIVATE DOCTORS LABORATORIES. ONLY 80 HAVE BEEN INSPECTED. AND WE FOUND PEOPLE DOING SOPHISTICATED TESTS WITH ALMOST NO TRAINING.

THE MOST SHOCKING PROBLEM WE FOUND...PAP SMEARS. STUDIES SUGGEST ONE IN EVERY FIVE LABS IN THIS COUNTRY MAY NOT BE READING PAP SMEARS CORRECTLY.

JANET COLEMAN (VICTIM):
"THERE'S NOTHING I CAN DO NOW. I FEEL TOTALLY USELESS."

THOMPSON:
JANET COLEMAN IS DYING A SLOW AND PAINFUL DEATH IN PRATT, VIRGINIA. TWO YEARS AGO SHE WENT TO HER DOCTOR FOR A PAP SMEAR. THE LAB REPORT CAME BACK NEGATIVE...BUT...

JANET COLEMAN (VICTIM):
"I KEPT GETTING WORSE. I DIDN'T GET ANY BETTER."

THOMPSON:
EIGHT MONTHS LATER, HER DOCTOR SENT IN ANOTHER TEST. THIS TIME, THE NEWS WAS DEVASTATING.

JANET COLEMAN (VICTIM):
"AND THE NEXT DAY THE DOCTOR CALLED AND SAID YOU'VE GOT CANCER."

THOMPSON:
HER DOCTOR ASKED NATIONAL HEALTH LABORATORIES IN VIENNA VIRGINIA - TO DOUBLE CHECK. THE CANCER HAD BEEN THERE ALL ALONG, BUT THE LAB HAD MISSED IT.

THE INITIAL REPORT IN JULY 1985 CLASS ONE BENIGN NEGATIVE...EIGHT MONTHS LATER - REEXAMINATION OF THAT SAME SLIDE...CLASS FOUR...VERY SERIOUS..."LARGE NUMBERS OF MALIGNANT CELLS."

IN THAT EIGHT MONTHS THE CANCER BECAME TOO ADVANCED FOR SURGERY. HER DOCTORS SAY NOW SHE ONLY HAS WEEKS TO MONTHS TO LIVE.

JANET COLEMAN (VICTIM)
"MAYBE GOD WILL SEE FIT TO SPARE ME...GIVE ME TIME. ESPECIALLY TO RAISE MY LITTLE GIRL UP SO SHE CAN TAKE CARE OF HERSELF BETTER.

THOMPSON:
THE NATIONAL HEALTH LAB IN VIRGINIA SERVES THE ENTIRE WASHINGTON AREA...AND HANDLES ABOUT 1,600 PAP SMEARS A DAY. FROM READING THIS REPORT, IT WOULD APPEAR THE LAB'S MEDICAL DIRECTOR...DOCTOR DAN FERIOZI...HAD PERSONALLY REVIEWED JANET COLEMAN'S CASE. BUT HE NEVER SAW IT. THE LAB JUST STAMPS HIS NAME ON THE REPORTS. AS FOR JANET COLEMAN, HER SLIDE WAS SCREENED BY A PART-TIME EMPLOYEE...WHO WAS FILLING IN ON THE NIGHT SHIFT.

THAT HAPPENS AT MANY LABS OTHER THAN NATIONAL HEALTH. SOME CYTOTECHNOLOIGISTS - THOSE WHO READ SLIDES FOR CANCER OR INFECTION OR VIRUSES IN CELLS, WORK ALL DAY AT ONE JOB AND WORK A SECOND SHIFT SOMEWHERE ELSE. SOME LABS EVEN ALLOW PEOPLE TO TAKE SLIDES HOME. AND FROM WHAT WE HAVE FOUND, TOO MANY LABS REQUIRE THEIR PEOPLE TO WORK TOO FAST.

EXPERTS SAY IT TAKES 10-12 MINUTES TO THROUGHLY REVIEW A PAP SMEAR FOR

PROBLEMS.

WE HAVE OBTAINED NATIONAL HEALTH LAB INTERNAL DOCUMENTS THAT SHOW THAT LARGE CHAIN OWNED BY REVLON REQUIRES ITS TECHNOLOGISTS TO READ ONE HUNDRED TWENTY PAP SMEAR SLIDES A DAY IN ORDER TO GET FULL PAY. THAT'S A SLIDE EVERY FOUR MINUTES. WHILE WE WERE AT METPATH IN KENSINGTON, ANOTHER NATIONWIDE CHAIN, TECNOLOGISTS WERE READING SLIDES IN LESS THAN A MINUTE. EXPERTS SAY THAT IS VERY DANGEROUS.

DR. HERB DICKERMAN (EXPERT):
"CYTOLOGY CAN NOT BE AN ASSEMBLY LINE INDUSTRY."

THOMPSON:
DR. HERB DICKERMAN, HEAD OF LABORATORY INSPECTION FOR NEW YORK STATE - CONSIDERED THE BEST INSPECTION PROGRAM IN THE COUNTRY.

THOMPSON:
"WHAT ABOUT A LAB THAT REQUIRES ITS TECHNOLOGISTS TO READ 120 SLIDES A DAY? DOES THAT SEND UP A FLAG FOR YOU?"

DR. HERB DICKERMAN (EXPERT):
"IT SENDS UP A BIG FLAG FOR ME. IT SENDS UP A FLAG THAT THE PERSON IS NOT AS INTERESTED IN THE QUALITY OF THE INTERPRETATION AS IN PRODUCTION. AND THAT'S ALWAYS DANGEROUS IN LABORATORY MEDICINE.

NEW YORK TECHNOLOGIST:
"YOU REALLY HAVE TO CONCENTRATE."

THOMPSON:
THIS NEW YORK HEALTH DEPARTMENT TECHNOLOGIST DOES AVERAGE TEN TO TWELVE MINUTES TO REVIEW A PAP SMEAR. THATS ONLY 35 TO 40 SLIDES A DAY. WE ASKED HER TO DEMONSTRATE HOW SHE WOULD HAVE TO DO IT IN 4 MINUTES.

NEW YORK TECHNOLOGIST:
"THIS STUFF IS JUST FLYING BY. I DON'T THINK I COULD DO A GOOD JOB DOING IT LIKE THIS. "I WOULDN'T BE FAIR TO THE PATIENT AT ALL."

THOMPSON:
THIS IS WHAT PAP SMEAR SCREENERS SEE THROUGH THE MICROSCOPE. ABNORMAL CELLS ARE EASY TO MISS. IN FACT SOME JUST WENT BY.

THIS IS A ROUTINE CELL...THIS IS A CANCER CELL...AND THESE ARE IN BETWEEN. THEY ARE DIFFICULT TO READ. BUT VERY IMPORTANT BECAUSE AT THIS STAGE THE CANCER IS STILL TREATABLE.

NEW YORK IS THE ONLY STATE THAT TESTS THE ACCURACY OF THE PEOPLE IN THE LABS WHO READ PAP SMEARS. WHAT IT HAS FOUND IS VERY ALARMING.

TWENTY PERCENT OF NEW YORK'S LABORATORIES FLUNKED PAP SMEAR PROFICIENCY TESTING...EVEN THOUGH THEY KNEW THEY WERE BEING TESTED. IT USED TO BE MUCH WORSE. WHEN THE STATE STARTED ITS ACCURACY TESTING IN 1972, 47 PERCENT - NEARLY HALF THE LABS FLUNKED. KNOWING ALL THAT - NO OTHER STATE HAS EVEN ATTEMPTED TO TEST THE ACCURACY OF THE PEOPLE WHO SCREEN PAP SMEARS.

THOMPSON:
OTHER STATES SAY IT IS JUST TOO EXPENSIVE AND THAT IT WOULD BE TOO HARD TO DO?

DR. HERB DICKERMAN (EXPERT):
"WHATS MORE EXPENSIVE A WOMAN WHO DIES UNNECESSARILY OR THE COST OF A PROGRAM?"

JANET COLEMAN (VICTIM):
"SOMETIMES I GET SO DEPRESSED AND DOWN I WISH IT WOULD BE SOON AND BE OVER WITH."

(END VIDEO TAPE)**

THOMPSON:
WE TALKED TO JANET COLEMAN A COUPLE OF WEEKS AGO. SATURDAY NIGHT, SHE DIED AT THE AT THE UNIVERSITY OF VIRGINIA HOSPITAL IN CHARLOTTESVILLE. WE HAVE TRIED TO TALK TO NATIONAL HEALTH LABS BY THE WAY. IT WON'T TALK ABOUT HER CASE OR ANYTHING ELSE.

YOU KNOW, EVERYONE WE TALKED TO IN OUR AREA SAYS IT IS TOO EXPENSIVE AND TOO DIFFICULT TO MAKE SURE TECHNOLOGISTS KNOW WHAT THEY ARE DOING. THE AMERICAN SOCIETY OF CYTOLOGY, IT IS THE CYTOLOGISTS THAT DO PAP SMEAR WORK, HAS OFFERED TO TEST LABS AND IT HAS THE EXPERTISE TO DO IT. BUT STATES HAVEN'T ACCEPTED THAT OFFER. ONLY 40 OF MORE THAN 1,000 LABS DOING PAP SMEAR WORK NATIONWIDE HAVE BOTHERED TO SIGN UP.

JUST KNOW THAT PAP SMEARS MAY HAVE A FAILURE RATE OF FROM 20-40%...IF YOU ARE HIGH RISK, YOU MIGHT CONSIDER A PAP SMEAR TWICE A YEAR TO CATCH ANY MISTAKES.

TONIGHT'S STORY HAS BEEN A WOMAN'S STORY. BUT OF COURSE LAB MISTAKES HAPPEN IN ALL KINDS OF TESTING. TOMORROW ON NEWS FOUR AT SIX, MORE ON WHICH TESTS AND WHICH LABS POSE THE GREATEST RISK. AND WE WILL HAVE MORE ON DEADLY MISTAKES TONIGHT ON NEWS FOUR AT ELEVEN.

"DEADLY MISTAKES" - PART II
NOVEMBER 17, 1987
WRC-TV NEWS
NEWS FOUR AT SIX

REPORTER: LEA THOMPSON
PRODUCER: RICK NELSON
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ANCHOR:

IT IS A TRAGEDY THAT COULD HAPPEN TO YOU. IT'S A STORY THAT AFFECTS EVERYONE BECAUSE THERE ISN'T ANYONE WHOSE DOCTOR WON'T SOMETIME SEND TESTS OFF TO A LABORATORY. LEA THOMPSON AND HER INVESTIGATIVE STAFF HAVE BEEN LOOKING INTO MEDICAL LABS. SHE JOINS US AGAIN TONIGHT WITH ANOTHER IN HER ALARMING SPECIAL REPORTS ON DEADLY MISTAKES.

LEA THOMPSON:

MOST PEOPLE ASSUME THAT THE GOVERNMENT WATCHES OVER MEDICAL LABORATORIES BECAUSE IT DOES WATCH OVER NEARLY EVERYTHING ELSE MEDICAL. BUT REGULATION OF LAB WORK IS SPOTTY AND FULL OF LOOPHOLES. LOOPHOLES THAT ALLOW FOR DEADLY MISTAKES.

WHEN YOU CONSIDER A LAB REPORT IS OFTEN CRITICAL TO A DIAGNOSIS LIKE CANCER, YOU CAN UNDERSTAND THAT A LAB REPORT CAN MEAN THE DIFFERENCE BETWEEN LIFE AND DEATH.

MOST LABS DO GOOD WORK. BUT LAB WORK IS NOT SOMETHING THAT SHOULD BE LEFT TO CHANCE.

(BEGIN VIDEO TAPE)**

ALEXANDRA SLOAN (VICTIM):

"SHOCK. I WAS IN SHOCK."

THOMPSON:

ALEXANDRA SLOAN WAS 29 YEARS OLD WHEN SHE WAS TOLD SHE HAD CANCER. TISSUE SAMPLES WERE SENT TO THE PATHOLOGIST AT THE ARLINGTON HOSPITAL LAB.

ALEXANDRA SLOAN (VICTIM):

"IT WAS HIS OPINION, AND HE HAD NO DOUBT IN HIS MIND, THAT IT WAS A MALIGNANCY. AND ON THAT INFORMATION MY DOCTOR DID A TOTAL HYSTERECTOMY."

THOMPSON:

THE LABORATORY'S DIAGNOSIS WAS WRONG. A LATER REVIEW OF THE SAMPLE SHOWED NO CANCER.

ALEXANDRA SLOAN (VICTIM):

"OF COURSE BY THAT TIME IT WAS TOO LATE TO STOP THE HYSTERECTOMY."

THOMPSON:

ALEXANDRA SLOAN WAS ABLE TO TO ADOPT, BUT SHE IS BITTER SHE CAN'T BEAR CHILDREN. SHE ALSO WISHES SHE HAD ASKED FOR A SECOND OPINION.

ALEXANDRA SLOAN (VICTIM):

"I WAS CASTRATED. I WAS UPSET TO KNOW I HAD CANCER. BUT I BELIEVE I WAS EVEN MORE UPSET TO KNOW THAT I DID NOT HAVE CANCER AND WAS GOING TO HAVE TO LIVE WITH WHAT HAD HAPPENED TO ME AND THAT I HAD BEEN BUTCHERED.

THOMPSON:

MEDICAL LABS ANALYZE EVERYTHING FROM BLOOD AND URINE TO CANCER AND

CHOLESTEROL. THEY TEST FOR DISEASES, CONDITIONS, GENETIC DEFECTS, FOR AIDS AND ALCOHOL AND DRUGS. THEY ARE LOCATED IN HOSPITALS, DOCTOR'S OFFICES AND COMMERICIAL LABORATORIES. AND WHILE MOST LABS ARE WELL RUN AND PROVIDE ACCURATE RESULTS, OUR FOUR MONTH INVESTIGATION HAS FOUND A DISTURBING NUMBER OF UNINSPECTED LABS, ERRORS AND DEADLY MISTAKES.

- ROBERT FENNER OF VIRGINIA HAD HODGKINS DISEASE. BUT THE LABORATORY MISSED IT WHEN ANALYZING THE TISSUE SAMPLE TAKEN FROM HIS NECK.
- CHARLIE ALSTON OF MARYLAND DID NOT HAVE PROSTATE CANCER. BUT THE LAB SAID HE DID. ALSTON SUFFERED THROUGH UNNECESSARY PROSTRATE SURGERY AND YEARS OF RADIATION TREATMENTS HE DIDN'T NEED.
- JUDY BURKE HAD BREAST CANCER BUT THE LABORATORY MESSED UP. HER DOCTORS NEVER TOLD HER ABOUT THE MISTAKE. SHE ONLY DISCOVERED IT BY ACCIDENT WHILE READING THROUGH THE FINE PRINT IN HER MEDICAL RECORDS.

JUDY BURKE (VICTIM)

"THEY COULD HAVE TAKEN THE LUMP OUT AND I'D HAVE BEEN CURED BECAUSE IT WAS VERY EARLY CANCER. AS IT TURNED OUT, IT WAS VERY ADVANCED CANCER EIGHTEEN MONTHS LATER."

THOMPSON:

THE DELAY ALLOWED THE CANCER TO SPREAD TO HER LYMPHNODES, AND THEN TO HER BRAIN. CHEMOTHERAPY AND RADIATION HAVE HER CANCER IN REMISSION BUT IT COULD RECUR AT ANY TIME.

JUDY BURKE (VICTIM):

"I CAN ACCEPT I HAD CANCER. I HAVE A REALLY HARD TIME ACCEPTING I HAD IT AS BAD AS I DID BECAUSE OF SOMEBODY ELSE'S MISTAKE."

THOMPSON:

IN A LAB MANY THINGS CAN GO WRONG. THE CALIBRATION OF MACHINES CAN BE OFF , THE AGE AND TEMPERATURE OF CHEMICALS CAN ALTER RESULTS. BUT THE BIGGEST THREAT IS HUMAN ERROR. CARELESS OR UNTRAINED OR TIRED TECHNICIANS WHO MISREAD OR MISINTERPRET OR SWITCH TEST SAMPLES.

DR. ANTHONY CORVELLI (EXPERT):

"AN INACCURATE RESULT CAN EITHER MISLEAD YOU INTO MAKING THE WRONG DIAGNOSIS OR POSSIBLY INTO THE WRONG TYPE OF THERAPY."

THOMPSON:

A FALSE BLOOD SUGAR READING CAN MASK DIABETES. A MISREAD STREP CULTURE COULD MEAN SCARLET FEVER AND DAMAGE TO THE HEART. A BAD PKU TEST...BRAIN DAMAGE TO AN INFANT.

TO ENSURE ACCURACY, MACHINES, CHEMICALS AND LABS MUST BE REGULARLY MAINTAINED AND INSPECTED AND TECHNICIANS MUST BE TESTED. NEW YORK IS THE ONLY STATE THAT INDEPENDENTLY TESTS ITS LABS FOR ACCURACY. YET, FIFTEEN PERCENT RECENTLY TESTED OUT MARGINAL OR BELOW IN NEW YORK. A STATE THAT HAS BEEN SCUTINIZING LABS FOR YEARS.

WHICH MAKES YOU WONDER ABOUT OUR AREA, WHERE NO INDEPENDENT TESTING IS DONE. MARYLAND AND D.C. DO INSPECT LABS BUT THEY DON'T INDEPENDENTLY TEST THE WORK OF THE LAB. VIRGINIA DOESN'T EITHER. IN FACT, VIRGINIA DOESN'T EVEN INSPECT LABS THAT DON'T DO INTERSTATE OR MEDICARE WORK. IN VIRGINIA AN ESTIMATED ONE THIRD OF THE COMMERCIAL LABS ARE NEVER VISITED BY AN INSPECTOR OF ANY TYPE.

NEWS FOUR LOOKED AT THE RECORDS OF ALL THE LABS IN OUR AREA THAT DO MEDICARE WORK. IN MARYLAND, FORTY THREE PERCENT OF THE THOSE LABS COULD NOT DOCUMENT THEY REGULARLY INSPECTED EQUIPMENT AND MATERIALS FOR ACCURACY. IN THE DISTRICT, 42 PERCENT...VIRGINIA, 27 PERCENT.

QUALITY CONTROL WAS CONSIDERED SO POOR AT SIX LABS IN MARYLAND THIS YEAR THAT MEDICARE THREATENED TO CUT OFF PAYMENTS. SOME WERE SMALL LABS LIKE THE LABORATORY MANAGMENT SERVICE OF BALTIMORE AND THE GUARI PATHOLOGICAL LABS OF

COCKEYSVILLE. OTHERS CITED BY MEDICARE WERE MEMBERS OF HUGE CHAINS LIKE THE ROCHE BIOMEDICAL LAB IN ELLICOTT CITY AND THE GIANT METPATH LAB IN KENSINGTON.

IT WAS A METPATH REPORT THAT RECENTLY PUT A 15 YEAR OLD VIRGINIA GIRL THROUGH AN INDIGNITY SHE WILL NEVER FORGET.

SHADOW INTERVIEW:
"NO CHILD SHOULD HAVE TO GO THROUGH THIS."

THOMPSON:
THIS WOMAN WANTS TO REMAIN ANONYMOUS FOR THE SAKE OF HER DAUGHTER. THE GIRL HAD GONE TO THE DOCTOR FOR A SORE IN HER MOUTH. THE LAB REPORT SAID IT WAS ORAL GONORREHEA.

SHADOW INTERVIEW:
SHE SAID IT'S IMPOSSIBLE. THERE'S NO WAY MOTHER. SHE DROPPED THE PHONE AND WENT INTO THE BATHROOM, LOCKED HERSELF IN THE BATHROOM AND CRIED."

THOMPSON:
NEXT CAME THE HUMILIATING EXAMINATIONS AND MASSIVE DOSES OF ANTIBIOTICS THAT MADE THE GIRL VERY SICK.

SHADOW INTERVIEW:
I THINK IT WAS TERRIFYING. IT WAS HUMILITATING. SHE WAS TOTALLY UNDONE."

THOMPSON:
SIX DAYS LATER, THE LAB CORRECTED THE REPORT. THE YOUNG GIRL NEVER HAD GONORRHEA.

THOMPSON:
DID YOU EVER ASK WHETHER IT MIGHT BE A MISTAKE?

SHADOW INTERVIEW:
"OH DEFINITELY."

THOMPSON:
WHAT DID THE DOCTOR SAY?

SHADOW INTERVIEW:
"THAT LABORATORIES DID NOT MAKE MISTAKES."

(END VIDEO TAPE)**

THOMPSON:
YOU KNOW IT IS NOT ONLY THE PUBLIC THAT ASSUMES THAT LAB REPORTS ARE INFALLIBLE AND FAILSAFE, SO DO DOCTORS. THERE IS A FALSE SENSE OF SECURITY AND NOWHERE IS IT MORE APPARENT THAN WHEN LAB WORK IS DONE RIGHT IN A PRIVATE DOCTORS OFFICE.

THAT IS A REAL PROBLEM. ONE STUDY DONE HERE SHOWS 38 PERCENT OF THE PEOPLE DOING LAB WORK IN YOUR DOCTORS OFFICE MAY HAVE NO LAB TRAINING AT ALL. WE'LL TALK ABOUT THAT AND A HOST OF OTHER SERIOUS DANGERS IN YOUR DOCTORS LAB TOMORROW NIGHT ON NEWS FOUR AT SIX. AND MORE ON DEADLY MISTAKES TONIGHT ON NEWS FOUR AT ELEVEN AS WELL.

"DEADLY MISTAKES" - PART III
NOVEMBER 18, 1987
WRC-TV NEWS
NEWS FOUR AT SIX

REPORTER: LEA THOMPSON
PRODUCER: RICK NELSON
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ANCHOR:

WE CONTINUE OUR SPECIAL REPORTS TONIGHT ON MEDICAL LABORATORIES. MOST OF US REALIZE THAT MEDICAL TESTS ARE TERRIBLY IMPORTANT. BUT MOST OF US TAKE THEM FOR GRANTED. LEA THOMPSON JOINS US AGAIN TONIGHT WITH MORE OF WHAT SHE AND HER INVESTIGATIVE STAFF HAVE DISCOVERED DURING THEIR FOUR MONTH LOOK AT LABS. TONIGHT, THE DANGERS IN THE LABS OF PRIVATE DOCTORS OFFICES.

LEA THOMPSON:

CONSIDER THIS, THE MAJORITY OF ALL THE LAB WORK DONE IN THE UNITED STATES IS NOW DONE IN PRIVATE DOCTORS LABS. WE HAVE ABOUT 30,000 DOCTORS IN OUR REGION.

YOU KNOW HOW MANY OF THEIR LABS HAVE BEEN CHECKED TO MAKE SURE THEIR MACHINES ARE WORKING RIGHT AND THEIR CHEMICALS AREN'T OUTDATED? 80. 80 OUT OF THOUSANDS OF LABS. LESS THAN ONE PERCENT OF PRIVATE DOCTORS LABS IN OUR REGION ARE INPSECTED. BUT THEY ARE DOING A MAJORITY OF THE WORK.

ALL 80 THAT HAVE BEEN LOOKED AT ARE IN MARYLAND. NOT ONE IN IN VIRGINIA OR THE DISTRICT. SURPRISED? I HAVEN'T FOUND MANY WHO AREN'T SURPRISED.

(BEGIN VIDEO TAPE)***

WOMAN ON THE STREET

"I WOULD BE SHOCKED IF THAT'S TRUE. IS THAT TRUE?

MAN ON STREET

"I FIGURED THAT WAS PART OF THE STANDARD PRACTICE. I DIDN'T KNOW THAT IT WAS NOT DONE ON A ROUTINE BASIS."

WOMAN ON STREET

"I JUST TAKE IT FOR GRANTED THAT THEY'RE ACCURATE AND THEY KNOW WHAT THEY'RE DOING."

THOMPSON:

MOST PEOPLE HAVE NO IDEA WHO DOES THEIR LAB WORK. THEY DON'T EVER THINK ABOUT IT. THESE DAYS, THE CHANCES ARE THE LAB IS IN YOUR DOCTORS OFFICE. AND, CHANCES ARE THAT LAB IS NOT INSPECTED OR REGULATED. AND, CHANCES ARE THE PEOPLE PERFORMING YOUR TEST ARE NOT ADEQUATELY TRAINED, QUALIFIED OR SUPERVISED.

DR. JOCELYN HICKS (CHILDREN'S HOSPITAL, WASHINGTON, D.C.):

"IT IS, I THINK BORDERING ON MALPRACTICE."

THOMPSON:

DR. JOCELYN HICKS IS HEAD OF LABORATORY MEDICINE AT WASHINGTON'S CHILDREN'S HOSPITAL. SHE RECENTLY SURVEYED WASHINGTON AREA DOCTORS WHO HAVE LABORATORIES IN THEIR OFFICES AND FOUND ONLY 13 PERCENT EMPLOYED REGISTERED MEDICAL TECHNOLOGISTS. THE REST OF THE PEOPLE PERFORMING THE TESTS WERE RECEPTIONISTS, TECHNICIANS, NURSES OR DOCTORS. MOST ALARMING, A FULL 38 PERCENT OF THEM HAD NO LABORATORY TRAINING AT ALL.

DR. JOCELYN HICKS (CHILDREN'S HOSPITAL, WASHINGTON, D.C.):
"I THINK WE'VE ALL BEEN RATHER WORRIED ABOUT THE QUALITY OF WHAT'S BEING DONE IN THE PHYSICIANS OFFICE."

THOMPSON:
DOCTORS ARGUE THAT AUTOMATED MACHINES MAKE TESTING FOOL PROOF. A NUMBER OF STUDIES SHOW THAT'S JUST NOT TRUE. A STUDY PUBLISHED IN THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION FOUND UNTRAINED PEOPLE USING A MACHINE LIKE THIS TO MEASURE GLUCOSE WERE CONSIDERABLY LESS ACCURATE THAN CERTIFIED TECHNOLOGISTS. A STUDY IN ILLINOIS LOOKED AT A WIDE VARIETY OF PROCEDURES, AND FOUND LABS THAT HAD CERTIFIED TECHNICIANS WERE 95% ACCURATE, NONCERTIFIED, 75% ACCURATE.

MORE AND MORE TESTING IS MOVING AWAY FROM HOSPITAL LABS LIKE THIS AND INTO THE DOCTORS' OFFICES. THE GOVERNMENT SAYS 60% OF ALL LAB WORK NOW DONE IN DOCTORS OFFICES. THE REASONS? BETTER EQUIPMENT AND QUICK RESULTS. BUT THE BIGGEST REASON IS MONEY. IN 1985, MEDICARE DECIDED DOCTORS CAN NO LONGER CHARGE AN EXTRA FEE FOR TESTS SENT OFF TO A LAB. BUT IF THOSE TESTS ARE PERFORMED IN THE DOCTOR'S OWN OFFICE. THERE IS NO LIMIT ON WHAT CAN BE CHARGED. SO THE AMOUNT OF TESTING DONE IN DOCTORS OFFICES HAS SKYROCKETED.

THOMPSON:
BUT THE REGULATION HASN'T KEPT PACE. ONLY THIRTEEN STATES HAVE FOUGHT THE DOCTOR'S LOBBIES AND VOTED TO REGULATE LABS. EVEN SO, MOST OF THOSE LAWS ARE VERY WEAK OR HAVE MAJOR DRAWBACKS.

DR. HERB DICKERMAN (N.Y. HEALTH DEPARTMENT):
"WE'RE PUTTING A LARGE NUMBER OF PEOPLE AT RISK BECAUSE OF OUR FAILURE TO OVERSEE IN THIS PARTICULAR AREA."

THOMPSON:
MARYLAND HAS HAD A REGULATION ON THE BOOKS SINCE 1975. BUT ONLY RECENTLY STARTED INSPECTING AND ITS LAW HAS A GLARING LOOPHOLE. MARYLAND CAN ONLY INSPECT LABS IF FOUR OR MORE DOCTORS OWN A GROUP PRACTICE TOGETHER.

THOMPSON:
AS LONG AS THEY DON'T HAVE FOUR OR MORE PHYSICIANS...THEY ARE NOT UNDER YOUR JURIDICTION?

DR. JACK DUBOY (MARYLAND HEALTH DEPARTMENT):
"THAT'S TRUE."

THOMPSON:
BUT YOU WOULD LIKE TO HAVE THEM?

DR. JACK DUBOY (MARYLAND HEALTH DEPARTMENT):
"MAYBE IT WOULD BE NICE FOR PUBLIC PROTECTION BUT THERE IS NO LAW ON THE BOOKS OF THE STATE OF MARYLAND TO LET US DO THAT."

THOMPSON:
MARYLAND'S LAW IGNORES A LOT OF LABS. MANY HMO'S, HEALTH CENTERS, WALK IN CLINICS - FACILITIES RUN BY HOSPITALS AND CORPORATIONS DO NOT FALL WITHIN THE LAW BECAUSE THEY ARE NOT ALWAYS "DOCTOR OWNED AND OPERATED".

PRIMEDICAL HAS TOLD THE STATE IT HAS 25 DOCTORS WORKING FOR IT. BUT, IT SAYS ONLY TWO WORK IN EACH OF ITS CLINIC LOCATIONS. SO IT CLAIMS IT IS EXEMPT FROM THE LAW.

AT THE HILLCREST CLINIC IN BALTIMORE, INSPECTORS FOUND LOTS OF PROBLEMS AND REPORTED THE LAB'S PRACTICES COULD LEAD TO "WRONG RESULTS." BUT NOW THE CLINIC HAS DROPPED DOWN TO THREE DOCTORS. THAT MEANS NO MORE INSPECTIONS.

THOUSANDS OF DOCTORS OPERATE ALONE BUT MARYLAND INSPECTORS CAN'T TOUCH THEIR LABS EITHER. DESPITE THE FACT THAT STUDIES IN PENNSYLVANIA SHOW THAT

SMALL LABS, LIKE THE ONES THAT ESCAPE REGULATION IN MARYLAND, PERFORM CONSISTENTLY WORSE THAN LARGE LABS.

ON URINE CULTURES, OFTEN USED TO DIAGNOSE BLADDER INFECTION AND KIDNEY DAMAGE, OVER HALF OF THE SMALL PENNSYLVANIA LABS PERFORMED UNACCEPTABLY. ON THROAT SCREENS THAT MIGHT DIAGNOSE PNEUMONIA OR RHEUMATIC FEVER, MORE THAN ONE THIRD OF THE LABS DID POORLY.

MORE THAN THREE QUARTERS OF THE SMALL LABS HAD TROUBLE WITH QUALITY CONTROL STANDARDS.

DR. DAVID WILKINSON (GEORGE WASHINGTON UNIVERSITY HOSPITAL, WASHINGTON, D.C.)
"IF QUALITY CONTROL IS POOR THEN YOU CANNOT RELY ON THE RESULTS."

THOMPSON:
QUALITY CONTROL IN A LABORATORY CAN BE COMPARED TO AN AIRLINE PILOT'S CHECKLIST. ITS THE ONLY WAY TECHNICIANS CAN VERIFY THAT THEIR CHEMICALS AND EQUIPMENT ARE WORKING CORRECTLY.

BUT A NEWS FOUR INSPECTION OF MARYLAND RECORDS SHOWS THAT QUALITY CONTROL IS THE NUMBER ONE PROBLEM.

DR. JACK DUBOY (MARYLAND HEALTH DEPARTMENT):
"PHYSICIANS HAVEN'T HAD TRAINING TO BE LABORATORIANS. A LOT OF TIMES WE'LL FIND THE PEOPLE DOING THE TESTS DON'T HAVE ANY FORMAL LAB TRAINING.

THOMPSON:
BECAUSE OF THAT, ANOTHER MARYLAND INSPECTION OFFICIAL TOLD US DOCTOR'S LABS PROBABLY SHOULD NOT BE ALLOWED TO DO MICROBIOLOGY - SOPHISTICATED TESTING THAT HAS TO BE READ BY PEOPLE RATHER THAN MACHINES.

BUT DEPSITE ITS PROBLEMS, MARYLAND'S LAW GOES FURTHER THAN OTHERS. IT REQUIRES ALL DOCTOR'S LABS TO BE TESTED FOR ACCURACY. MARYLAND PATIENTS DO FARE FAR BETTER THAN PATIENTS IN VIRGINIA OR THE DISTRICT, WHERE ABSOLUTELY NOTHING IS DONE TO IMPROVE QUALITY IN DOCTOR'S LABS.

IN FACT THESE HAIR STYLISTS ARE REQUIRED TO UNDERGO MORE TRAINING AND SCHOOLING THAN THE PEOPLE WHO PERFORM YOUR MEDICAL TESTS IN DOCTOR'S OFFICES IN VIRGINIA AND THE DISTRICT

WOMAN ON STREET:
"I WOULDN'T WANT TO GO TO A PHYSICIAN WHERE I KNOW THE LABORATORIES ARE NOT INSPECTED."
THOMPSON:
WELL THEY ARE NOT.

WOMAN ON STREET:
"THEY'RE NOT?"

SECOND WOMAN ON STREET:
"I JUST ASSUME HE KNOWS WHAT HE'S DOING."

THIRD WOMAN ON STREET:
"I SUPPOSE IT'S LIKE EVERYTHING. WE HAVE TO HAVE SOME TRAGEDIES BEFORE THEY GET REGULATED."

(END VIDEO TAPE)***

THOMPSON:
LABS IN PRIVATE DOCTORS OFFICES HAVE BECOME MINI PROFIT CENTERS. MANUFACTURERS OF INSTRUMENTS LULL DOCTORS INTO THINKING THEIR MACHINES ARE FAILSAFE AND FOOLPROOF. DOCTORS LET MANUFACTURERS SHOW THEIR REGULAR EMPLOYEES HOW TO RUN THE MACHINES RATHER THAN HIRING A TECHNOLOGIST WHO KNOWS WHAT HE OR SHE IS DOING.

IT IS A RECIPE FOR DISASTER. A RECIPE FOR A DEADLY MISTAKE. TOMORROW ON NEWS FOUR AT SIX WE WILL TELL YOU HOW THE GOVERNMENT HAS ALLOWED ALL THIS TO HAPPEN. TONIGHT ON NEWS FOUR AT ELEVEN WE CONTINUE THIS SERIES OF SPECIAL REPORTS.

D.C. STILL ALLOWS IT TO DO BUSINESS. IN FACT, IT IS DOING PRE-MARITAL BLOOD SCREENING FOR THE DISTRICT GOVERNMENT.

THE FEDERAL GOVERNMENT'S REPORT CARD IS EVEN WORSE WHEN IT COMES TO REGULATING LABORATORIES IN PRIVATE DOCTOR'S OFFICES.

THE WAY PENNSYLVANIA INSPECTS LABORATORIES IN DOCTOR'S OFFICES. IS WIDELY CONSIDERED TO BE THE BEST IN THE COUNTRY. JOSEPHINE BARTOLO HEADS THAT INSPECTION PROGRAM.

JOSEPHINE BARTOLO (PENNSYLVANIA HEALTH DEPT.):
"THE FEDERAL GOVERNMENT HAS NEGLECTED A LARGE PORTION OF THE LABORATORY COMMUNITY."

THOMPSON:
THE GOVERNMENT ESTIMATES 60% OF ALL MEDICAL TESTS ARE NOW DONE IN DOCTOR'S OFFICES, YET THE GOVERNMENT DOESN'T INSPECT OR REGULATE ANY OF THEM.

JOSEPHINE BARTOLO (PENNSYLVANIA HEALTH DEPT.):
"IT DOESN'T MAKE SENSE TO REGULATE ONE AREA AND NOT ANOTHER."

THOMPSON:
ONLY 13 STATES LOOK AT PRIVATE DOCTORS LABS. MARYLAND DOES, D.C. AND VIRGINIA DO NOT.

BOB JOHNSON (WIDOWER):
"WHAT PRICE DOES VIRGINIA PUT ON LIFE?"

THOMPSON:
FAMILIES OF VICTIMS BELIEVE IF ALL LABS WERE SUBJECT TO STRINGENT REGULATIONS, AND ALL TECHNICIANS WERE TESTED, QUALIFIED AND SUPERVISED, THEN THEIR LOVED ONES WOULD BE ALIVE TODAY.

BOB JOHNSON (WIDOWER):
"IT IS SO COMPLETELY INEXCUSABLE, SHE WOULD HAVE SURVIVED."

(END VIDEO TAPE)**

THOMPSON:
CONGRESS ORDERED THE HEALTH CARE FINANCING ADMINISTRATION TO MAKE A RECOMMENDATION ON WHETHER PRIVATE DOCTORS LABORATORIES SHOULD BE INSPECTED. THAT STUDY WAS DUE IN APRIL. IT STILL ISN'T OUT YET. IT IS A CONTRADICTION FOR MEDICARE TO INSIST ON INSPECTION AND TESTING OF COMMERCIAL LABS BUT TO LEAVE DOCTORS LABS ALONE. ESPECIALLY IF YOU CONSIDER THAT IS WHERE THE MAJORITY OF THE WORK IS BEING DONE

AS JANICE JOHNSON'S HUSBAND WARNED US. YOU JUST CAN'T TAKE LABORATORY TESTING FOR GRANTED. YOU HAVE TO LOOK OUT FOR YOURSELF. TOMORROW ON NEWS FOUR AT SIX WE'LL TELL YOU HOW TO DO THAT. AND TONIGHT ON NEWS FOUR AT ELEVEN WE'LL ALSO HAVE MORE ON DEADLY MISTAKES.

DAY. THATS FOUR TIMES THE RECOMMENDATIONS FOR ACCURACY.

BOB JOHNSON (WIDOWER):
"HOW COULD THIS HAVE POSSIBLY HAPPENED? IT CAN BE PROVEN THAT THEY MISSED IT TWICE. MY CONTENTION IS, AND IT WAS JAN'S THAT THEY MISSED IT THREE, FOUR, FIVE TIMES."

THOMPSON:
EVERYWHERE WE LOOKED WE FOUND MORE PROBLEMS WITH PAP SMEARS THAN ANYTHING ELSE, YET ONLY ONE STATE BOTHERS TO TEST THE ACCURACY OF TECHNOLOGISTS WHO READ PAP SMEARS. IT ONLY HAPPENS HERE IN ALBANY, THE CAPITAL OF NEW YORK.

DR. HERB DICKERMAN (N.Y. HEALTH DEPT.):
"THE BOTTOM LINE IS THE CARE OF THE PATIENT."

THOMPSON:
DR. HERB DICKERMAN IS HEAD OF THE NEW YORK STATE'S LABORATORY INSPECTION PROGRAM. HE THINKS IT IS HORRENDOUS THAT EVERY STATE IS NOT TESTING LABS THAT DO PAP SMEARS.

DR. HERB DICKERMAN (N.Y. HEALTH DEPT.):
"IF THAT CELL IS READ ERRONEOUSLY YOU'RE DOOMED."

DR. JACK DUBOY (MARYLAND HEALTH DEPT.):
"IT IS EXTREMEMLY DIFFICULT TO COME UP WITH A PROFICIENCY TEST OF THIS TYPE. DIFFICULT, TIME CONSUMING AND A COSTLY TYPE PROGRAM

DR. HERB DICKERMAN (N.Y. HEALTH DEPT.):
"YOU CAN'T LOOK AT IT IN TERMS OF DOLLARS AND CENTS."

THOMPSON:
EXPERTS SAY THE GOVERNMENT SHOULD BE DOING MORE TO ENSURE ACCURACY AND PRECISION IN LABORATORIES. BUT ACUTALLY, THE GOVERNMENT IS DOING FAR LESS.

THE CENTERS FOR DISEASE CONTROL USED TO TEST LABS FOR ACCURACY. TWO YEARS AGO IT ABANDONED THE PROGRAM. NOW LABS ARE TESTED BY PROFESSIONAL ASSOCIATIONS THAT THE LABS HIRE THEMSELVES. THE LABS ARE EVEN TOLD WHEN THEY ARE BEING TESTED.

IF THAT ISN'T EASY ENOUGH, THE GOVERNMENT ESTABLISHED NEW GUIDELINES THREE MONTHS AGO TO MAKE IT EVEN EASIER TO STAY IN THE MEDICARE PROGRAM. TO PASS BLOOD WORK AND CHEMISTRY TESTS, LABS ONLY NEED A SEVENTY. AS ANY STUDENT KNOWS, THAT'S BARELY A PASSING GRADE ON MOST HIGH SCHOOL CHEMISTRY TESTS, AND IN THIS CASE, A PATIENT'S LIFE MAY BE AT STAKE.

DR. HERB DICKERMAN (N.Y. HEALTH DEPT.):
"THE FEDERAL GOVERNMENT HAS MOVED AWAY FROM THIS AREA AND HAS LEFT US OUT THERE ALONE."

THOMPSON:
EVEN WHEN THE GOVERNMENT FINDS A DANGEROUS LAB, IT HAS LITTLE POWER EXCEPT TO WITHHOLD MEDICARE MONEY.

THE MEDI-CENTER LAB IN CATONSVILLE, MARYLAND WAS CUT OFF FROM MEDICARE MONEY IN FEBRUARY OF THIS YEAR. INSPECTORS CALLED THE LAB A "SERIOUS THREAT" TO PATIENTS. BUT WITHIN TWO MONTHS THE LAB WAS REINSPECTED AND BACK IN THE PROGRAM AGAIN.

THE B&W STAT LAB ON GEORGIA AVENUE IN THE DISTRICT IS ONE OF A VERY FEW LABS EVER EXPELLED FROM MEDICARE. CRIMINAL CHARGES WERE FILED AGAINST THE LAB A FEW YEARS AGO. THE LAB ADMITTED IT DID NOT DO HUNDREDS OF TESTS IT WAS PAID FOR. INSPECTORS ALSO SAY LEAD POISONING TESTS ON CHILDREN WERE SENT TO THE LAB BUT THERE WERE NO RECORDS THE TESTS WERE EVER DONE.

THE LAB PAID A THOUSAND DOLLAR FINE, AND NO LONGER DOES MEDICARE WORK. BUT

"DEADLY MISTAKES" - PART IV
NOVEMBER 19, 1987
WRC-TV NEWS
NEWS FOUR AT SIX

REPORTER: LEA THOMPSON
PRODUCER: RICK NELSON
RESEARCHER: SHEILA DUFFY
PHONE: (202)885-4883

ANCHOR:
ALL THIS WEEK ON NEWS FOUR AT SIX WE HAVE BEEN BRINGING YOU SOME ALARMING NEWS ABOUT MISTAKES ON THE MEDICAL TESTS YOUR DOCTOR REQUESTS. THE QUESTION WE KNOW EVERYBODY IS ASKING IS HOW CAN THIS BE AND WHY HASN'T ANYBODY DONE ANYTHING ABOUT IT. LEA THOMPSON.

LEA THOMPSON:
WELL, NOW THINGS ARE STARTING TO HAPPEN. AS A RESULT OF OUR SERIES OF SPECIAL REPORTS THIS WEEK, D.C. CITY COUNCILMAN JOHN WILSON SAYS ON TUESDAY OF NEXT WEEK HE WILL INTRODUCE LEGISLATION THAT WILL GIVE MORE PROTECTION TO D.C. CITIZENS. WE DON'T HAVE ALL THE DETAILS OF THAT LEGISLATION YET, IT'S JUST NOW BEING WRITTEN. BUT WE'LL FILL YOU IN AS SOON AS WE DO.

BUT, TO ANSWER DAVE'S QUESTION AS TO WHY MORE HASN'T BEEN DONE BEFORE NOW. MOST PEOPLE - MOST DOCTORS - TOOK LAB WORK FOR GRANTED. THEY ASSUMED WAS IS RIGHT. THERE HASN'T BEEN A HUE AND CRY UP UNTIL NOW BECAUSE MOST PEOPLE DIDN'T KNOW HOW MUCH BAD LAB WORK WAS GOING ON. AFTER ALL, IT'S NOT IN A LAB OR DOCTORS BEST INTEREST TO TALK ABOUT THEIR DEADLY MISTAKES.

MOST OF US ASSUME THE GOVERNMENT HAS BEEN REGULATING LABS. BUT AS WE HAVE SHOWN YOU REGULATION OF MEDICAL LABORATORIES IS SPOTTY AND THE LOOPHOLES ARE LARGE. THERE ARE SOME STATES THAT ARE DOING IT RIGHT. WE TRAVELED UP AND DOWN THE EAST COAST TO SHOW YOU HOW THEY DO IT. WE DIDN'T HAVE TO GO FAR, HOWEVER, TO FIND MASSIVE PROBLEMS CLOSE TO HOME.

(BEGIN VIDEO TAPE)**

THOMPSON:
ERIKA HEDEN'S LABORATORY FAILED TO DIAGNOSE THE SERIOUSNESS OF HER CANCER. SHE DIED AT ACE 28.

SANDRA MAGRUDER'S DOCTOR SENT HER PAP SMEARS TO A LAB THAT ADVERTISED LOW PRICES, QUICK SERVICE AND MISREAD HER PAP SMEAR TWICE IN NINE MONTHS. SHE DIED AT AGE 36.

JANICE JOHNSON WAS DILIGENT ABOUT GETTING AN ANNUAL CHECK UP AND YEARLY PAP SMEAR. BUT HER PAP SMEARS WERE MISREAD AT LEAST TWICE BY THE SAME PERSON. SHE DIED AT AGE 35.

BOB JOHNSON (JANICE JOHNSON'S HUSBAND):
"I DON'T THINK I'LL EVER FORGET HEARING HER ASKING HER MOTHER, HOW COULD THIS BE HAPPENING TO MY BODY?"

THOMPSON:
JANICE JOHNSON WAS A WIFE AND MOTHER IN THE PRIME OF HER LIFE. HER PAP SMEARS WERE REVIEWED BY A WOMAN WHO WORKED ALL DAY AT NORTHERN VIRGINIA DOCTOR'S HOSPITAL AND THEN REVIEWED SLIDES AFTER WORK.

PAP SMEARS ARE NOT EASY TO READ. EXPERTS SAY TO BE ACCURATE A PERSON SHOULD REVIEW NO MORE THAN SEVENTY FIVE SLIDES A DAY. BUT THE WOMAN WHO LOOKED AT JANICE JOHNSON'S SLIDES ADMITS SHE SOMETIMES SCREENED THREE HUNDRED SLIDES A

"DEADLY MISTAKES" - PART V
NOVEMBER 20, 1987
WRC-TV NEWS
NEWS FOUR AT SIX

REPORTER: LEA THOMPSON
PRODUCER: RICK NELSON
RESEARCHER: SHEILA DUFFY
PHONE: (202)885-4883

ANCHOR:

ALL THIS WEEK NEWS FOUR HAS BEEN REPORTING ON THE RESULTS OF A FOUR MONTH INVESTIGATION INTO MEDICAL LABORATORIES IN OUR AREA. NOW THAT WE KNOW THERE ARE MASSIVE PROBLEMS IN MEDICAL LABS, LEA THOMPSON JOINS US TONIGHT TO TELL YOU HOW TO PROTECT YOURSELF.

THOMPSON:

WE'VE TALKED THIS WEEK ABOUT ALL THE THINGS THAT CAN AND DO GO WRONG. ABOUT THE LACK OF CHECKS AND BALANCES, ABOUT MACHINES THAT AREN'T CALIBRATED, ABOUT PEOPLE WHO AREN'T TRAINED. ABOUT THE LACK OF INSPECTION AND TESTING. ALL THIS WEEK YOU HAVE MET THE VICTIMS OF DEADLY MISTAKES.

TONIGHT WE WANT TO TELL YOU HOW TO KEEP A TERRIBLE TRAGEDY FROM HAPPENING TO YOU.

(BEGIN VIDEO TAPE)**

THOMPSON:

HIGH TECH MACHINES DO CRITICAL MEDICAL WORK IN THOUSANDS OF WASHINGTON AREA LABS. BUT THEY ARE ONLY AS GOOD AS THE ANONYMOUS TECHNICIANS WHO RUN THEM. HOW CAN YOU PROTECT YOURSELF AGAINST MISTAKES? ASK THE PEOPLE WITH FIRST HAND KNOWLEDGE. THE VICTIMS.

RAY HITT (VICTIM):

"I HAD A REAL BAD WHITE BLOOD CELL COUNT THAT SHOWED I WAS INFECTED OR HAD LEUKEMIA OR SOMETHING AND IT WAS DONE OVER AND SHOWED IT WAS OKAY. NO PROBLEM AT ALL.

THOMPSON:

RAY HITT'S DOCTOR DID THE RIGHT THING. ALEXANDRA SLOAN'S DID NOT.

ALEXANDRA SLOAN (VICTIM):

"NOW I KNOW I SHOULD HAVE DEMANDED SECOND OPINIONS OF THEIR LABORATORY."

THOMPSON:

ALEXANDRA SLOAN KNOWS THAT NOW. A SECOND OPINION WOULD HAVE CAUGHT THE LAB ERROR. SHE WOULD NOT HAVE HAD A HYSTERECTOMY AND SHE COULD HAVE HAD CHILDREN.

JUDY BURKE (VICTIM):

"THE NORMAL PERSON WOULDN'T QUESTION THE TESTING. THEY'LL QUESTION THE DOCTOR AND FIND OUT WHAT THE TEST WAS FOR, BUT NOT THE ACTUAL DIAGNOSIS ON THE TESTING."

THOMPSON:

JUDY BURKE KNOWS NOW YOU HAVE TO QUESTION LAB RESULTS JUST AS MUCH AS DOCTORS ADVICE. HER LAB MISSED HER BREAST CANCER AND IT SPREAD THROUGHOUT HER BODY.

DR. ARTHUR FRANK (WASHINGTON, D.C. PHYSICIAN):

"I THNK WHAT YOU HAVE TO DO IS RECOGNIZE LABORATORIES ARE A BUNCH OF HUMAN BEINGS RUNNING A BUNCH OF MACHINES AND THAT ERRORS CREEP INTO THAT SYSTEM."

THOMPSON:
THE FACT IS, FROM WHAT WE HAVE FOUND, LAB ERRORS OCCUR MORE FREQUENTLY THAN YOU MIGHT THINK. OFTEN THEY ARE HIDDEN EVEN TO PATIENTS.

JOANNE JONES (VICTIM):
"THEY MUST NOT BE PAYING ATTENTION TO WHAT THEY'RE SUPPOSED TO BE DOING."

THOMPSON:
JOANNE JONES HAD TO HAVE A HYSTERECTOMY AT AGE 22. HER LAB MISSED THE CANCER ON HER PAP SMEAR. HER DOCTOR DIDN'T TELL HER ABOUT THE MISTAKE UNTIL SHE ASKED.

JOANNE JONES (VICTIM):
"I NEVER EVEN KNEW THERE WERE LABS. I JUST THOUGHT THEY DID IT RIGHT THERE IN THE DOCTOR'S OFFICE."

DR. HERB DICKERMAN (N.Y. HEALTH DEPT.):
"I WOULD ASK MY PHYSICIAN WHERE THAT LABORATORY WORK WAS BEING DONE."

DR. JACK DUBOY (MARYLAND HEALTH DEPT.):
"ASK WHO IS DOING HIS WORK, TECHNICIAN, SECRETARY, NURSE, WHATEVER."

JOSEPHINE BARTOLO (PENNSYLVANIA HEALTH DEPT.):
"I WOULD NOT GO TO HAVE MY LABORATORY WORK PERFORMED IN A LABORATORY THAT WAS NOT BEING REGULATED."

THOMPSON:
THERE ARE LITERALLY HUNDREDS AND HUNDREDS OF COMMERICAL LABS IN OUR AREA, AN ESTIMATED 28,000 LABS IN PRIVATE DOCTORS OFFICES. HOW DO YOU KNOW WHERE YOUR WORK IS BEING DONE, WHAT KIND OF TECHNICIAN IS DOING IT AND IF THAT LAB IS LICENSED, INSPECTED AND TESTED? YOU HAVE TO ASK. BUT YOU HAVE TO BE INFORMED. LET'S TALK ABOUT INSPECTION FIRST.

ALL HOSPITALS IN OUR AREA ARE INSPECTED. ALL COMMERICAL LABS ARE INSPECTED IN MARYLAND AND THE DISTRICT. HOWEVER, IN VIRGINIA ONLY THOSE LABS THAT DO MEDICARE OR INTERSTATE WORK ARE INSPECTED. THAT MEANS AN ESTIMATED ONE THIRD OF THE COMMERICAL LABS IN VIRGINIA ARE NOT INSPECTED.

WOMAN ON STREET:
"I AM LIKE SHOCKED. THEY REALLY ARE NOT REGULATED?"

THOMPSON:
MOST ARE NOT.

WOMAN ON STREET:
"THAT SURPRISES ME. WHO WATCHES OVER THEM?"

THOMPSON:
NOBODY.

WOMAN ON STREET:
"OH, COME ON."

THOMPSON:
THE GOVERNMENT SAYS 60% OF ALL LAB WORK IS NOW BEING DONE IN PRIVATE DOCTORS OFFICES. MARYLAND HAS INSPECTED ONLY 80 OF THEM. D.C. AND VIRGINIA DON'T INSPECT AT ALL.

BUT EVEN IF THE LAB IS INSPECTED, IT DOESN'T MEAN ITS PEOPLE CAN DO THE WORK. A STUDY DONE IN D.C. SHOWED 38% OF THE PEOPLE DOING WORK IN DOCTORS OFFICE LABS HAD NO LAB TRAINING AT ALL.

SO WHICH LABS ARE TESTED TO MAKE SURE THEY KNOW WHAT THEY ARE DOING. MARYLAND REQUIRES ALL LABS TO BE TESTED. D.C. DOES TOO, EXCEPT FOR LABS IN

PRIVATE DOCTORS OFFICES. VIRGINIA ONLY REQUIRES TESTING OF THE TECHS IF THEY DO MEDICARE OR INTERSTATE WORK. THAT LEAVES LOTS OF COMMERCIAL AND ALL DOCTORS LABS UNTESTED IN VIRGINIA.

AND YOU NEED TO KNOW ABOUT PAP SMEARS. THAT'S WHERE WE FOUND MOST OF THE PROBLEMS. EVEN THOUGH PAP SMEARS MAY BE WRONG 20-40% OF THE TIME. NONE OF OUR JURISDICTIONS TESTS THE TECHNOLOGISTS WHO READ THEM.

MOST OF ALL THOUGH, LISTEN TO JANET COLEMAN. SHE KNEW SHE WAS SICK, BUT SHE WAS LULLED INTO A FALSE SENSE OF SECURITY WHEN HER PAP SMEAR CAME BACK NEGATIVE. THE LAB HAD MADE A MISTAKE. IN REALITY, THAT SLIDE WAS FULL OF CANCER CELLS. NOW SHE WILL PAY FOR SOMEONE'S ELSE'S MISTAKE WITH HER LIFE.

JANET COLEMAN (VICTIM):
"I'D LIKE TO WARN OTHER WOMEN. GET A SECOND OPINION."

(END VIDEO TAPE)•••

THOMPSON:
WE TALKED TO JANET COLEMAN JUST A COUPLE OF WEEKS AGO. SHE DIED LAST SATURDAY NIGHT AT THE UNIVERSITY OF VIRGINIA HOSPITAL IN CHARLOTTESVILLE.

A FEW MORE THOUGHTS. WHO DOES THE BEST WORK? PROBABLY HOSPITALS. YOU CAN ALWAYS ASK YOUR DOCTOR TO HAVE YOUR LAB WORK SENT TO ONE. BUT WE'RE TOLD ON THE WEEKENDS, HOSPITALS LABS ARE OFTEN OVERLOADED AND SHORTSTAFFED.

IF YOUR DOCTOR IS USING A MAIL ORDER LAB THERE IS REASON TO ASK WHY. STUDIES SHOW SMALL DOCTORS LABS ARE MORE APT TO MAKE MISTAKES THAN BIG ONES. AND, THAT UNLESS A DOCTOR HAS A MEDICAL TECNOLOGIST WORKING FOR HIM, A PERSON WITH A DEGREE, HE PROBABLY SHOULD NOT BE DOING SOPHISTICATED TESTS WHICH MUST BE READ BY PEOPLE RATHER THAN MACHINES.

AND, ASK FOR A COPY OF YOUR LAB REPORT. YOU HAVE EVERY RIGHT TO READ IT AND TO ASK QUESTIONS ABOUT WHAT IT SAYS. THERE IS NO QUESTION YOU HAVE TO LOOK OUT FOR YOURSELF. TO DO ANYTHING LESS LEAVES ROOM FOR A DEADLY MISTAKE.

TONIGHT ON NEWS FOUR AT ELEVEN, ONE LAST INSTALLMENT ON THIS TRADEGY THAT COULD HAPPEN TO YOU.

Ms. THOMPSON. Senator, some other thoughts, if I may. We discovered that some cytotechnologists work all day in one job and then go to another job, another shift, somewhere else. Many labs, as you already know, pay on a piecemeal basis, and some labs even allow people to take work home.

It is hard to imagine that the woman who looked at Janice Johnson's slides says that she read sometimes 300 slides a day.

Pap smears, of course, as you are well aware, as we tried to show you, are not easy to read. Having seen cytotechnologists in action, I have enormous respect for them. It is not a job that I could do, frankly. It is a job that fewer and fewer people apparently want to do. The pay is low. It is too low to attract many people. There are schools that train cytotechs closing down all over the country. And it is getting very hard to find a trained person, which I think also means, then, that it is perhaps putting more work on the people who are already trained.

Everybody we talked to in our area says it is too expensive and too difficult to make sure that technologists know what they are doing.

Dr. Herb Dickerman, who spent a great deal of his time—and I want to say publicly that we appreciate him helping us with our story—will tell you that you can do it; it is not too expensive, and it is not too difficult.

I anticipate that one of the questions you might ask is whether we have any estimates about how many mistakes are made in this overall area of Pap smears and whether there are more Pap smear mistakes than there are other laboratory mistakes.

Our gut reaction—and I am afraid that is all I can give you—our gut reaction is that there are more Pap smear mistakes, primarily because they are so prone to doctor error in taking the sample and then also technical error in reading that sample.

We found more lawsuits involving Pap smears than any other test. We believe that is due to the fact, though, that if a mistake is made on a Pap smear, it is usually deadly, and deaths at a young age do have a tendency to turn into lawsuits. A Pap smear is one of the few tests, also, that you hang onto a while; the evidence thus is kept, which means it is easier to bring a case.

Most people, I believe—most doctors, I believe—take lab work for granted, just like I think you are going to find in the case of Barbara Arbuckle. People assume in this country that lab tests are correct.

We suspect that there are a lot more Pap smear errors than anybody knows. The people we interviewed said that they found out about their errors only by accident. Let's face it. It is not in the labs' or the doctors' best interest to tell people that they made a mistake.

Thank you very much.

Senator ADAMS. Thank you, Ms. Thompson.

What has really concerned me—and we don't want to go into questions yet, because I want to hear from Ms. Arbuckle—is that there is no countervailing or back pressure. All the pressures go on the cytotechnologist area to do more for less and without a back pressure, the system is collapsing. And that is what we are trying to develop here.

But I want to go to Ms. Arbuckle, because I have seen and reviewed your case, and I think the public needs to know about this. Barbara?

Ms. ARBUCKLE. Thank you, Senator Mikulski, Senator Adams, ladies and gentlemen.

The story I have to tell is not a fun one, and it was not fun to go through. I was a person, and am still a person who very much cares about my health. And at the age of 14, I went in and started having annual Pap smears. At that time, I was experiencing unusual menstrual periods.

I went on the pill to regulate them, and it helped; it put them under control. From what I understand, a lot of girls go through this, and the doctors put them on the pill and regulate it, and they seem to have no problem.

In 1983, I moved back to Seattle from the State of Texas, and I went off the birth control. Within a few months, things were just as crazy as ever. So I went to a doctor, telling him how irregular they were. He ran a test, a Pap smear, and he put me back on birth control. The test came back fine.

There, for several months, it seemed to regulate it again. In 1984, in that time period, the problem started up again. I went from that problem to the problem of having very heavy discharges. Then I went to the problem that any time I made love, I bled.

I also had been on birth control for a numerous amount of years and was a smoker.

In August of 1985, I was seeing my doctor quite frequently, because he was telling me I had an ulcer on my cervix and to use this cream, and that should take care of it.

I missed one appointment for the fact that my sister had moved back home, and we had stayed up very late one night, chatting away. The following week, on a Monday night, I was sitting around, talking with my sister, and turned on the news. A program called "Accu-Pap" came on. A gentleman you will hear from today, Dr. Hasselbrack, was doing this program.

As Dorothy and I were sitting there, talking, all of a sudden I could hear him describing things I was going through, and it caught both of our attentions immediately, because I had talked to my sister about it.

There was a number that went across the screen. I took it down. The next morning, I called it. I talked to two different gentlemen who asked me several questions, and I went through what I was experiencing, and they asked me why I hadn't had a biopsy.

I said, "Gosh, I don't know. I'm no doctor. I'm just a person." They suggested I have one done.

That afternoon, I had an appointment with my doctor. I told him what I had seen and what I had heard. He did what they call a quick exam and the next day had me set up with another doctor to have the biopsy done, which was a Wednesday. On Friday afternoon, that doctor called me at home and asked me to come in to his office.

I said, "No. Whatever you have to say, you tell me over the phone." He didn't like the idea, but he did it.

When he told me I had cancer, I froze. And then he explained to me that I had to be in the hospital very early Monday morning, because he wanted to run what they call a "cone" and a D and C. When I got to the hospital Monday morning, he told me he thought I would be an outpatient, but if things were not what they thought they should be, he would be keeping me overnight. When I woke up, he was keeping me overnight.

The next day, he walked into my room, and he had the most horrifying look on his face, and with no other words but: "We are in deep trouble, kid." It wasn't, "Hi. How are you doing today?"

He sat down and explained to me that the cancer was much more in depth than they ever assumed it would be; that he had gotten hold of some other doctors, some specialists in the field, that they would be getting hold of me immediately; that I had to have several tests run through the next three weeks, and that generally they do no kind of surgery after a cone and D and C for at least six weeks, but because the cancer was so extensive, I had to have it done in three weeks. He was speaking a radical hysterectomy. I was 23 years old.

I was paranoid; I was so scared. My sister helped me through these times. In the next three weeks, I learned I was going to lose my job because I was under a 90-day probation by six days.

I went to our State for help, to the Welfare Department. I was in there numerous times in those three weeks. I ended up with medical coupons, no food stamps—that was my problem—find another way to eat. I ended up with $42 the first month and 200-something the second. I cannot quote that figure. The rest was my problem—how to pay my rent, how to put food in my stomach, and how to pay my electricity. Unfortunately, that winter was a harsh one in Seattle.

Every day, I went to work, knowing what I was facing. I came home, and my sister was there. She took care of me very well. I do say if a person ever goes through this experience, your family and friends are very important, and please let them help you.

On the 27th of October, I went in the hospital. On the 28th, they did the surgery. I then had until that Friday to find out whether it had gone any further or not. That week was a hard one, worrying. I was drugged up tremendously, on all kinds of painkillers; I had tubes and needles going in and out of my body. On the second day, I did not want to move, and they made me move out of that bed; they made me walk, because they wanted me to stretch back out.

I went home after nine days. The following Sunday was my 24th birthday. That even, I ended up back in the hospital. I had a bladder infection. They sent me home after giving me some medication. I had a catheter in that was kept in for four weeks. They arrogated the catheter.

The very next night, I was back in the hospital again. I was allergic to the medication. It dehydrated me; it made me extremely sick. And they had to run some more tests to see what kind of medication they could put me on.

They put medications into me for the dehydration, and I went home. The next four days, I heard from a nurse every day, wanting to know if I was okay.

It took several weeks to get back, moving. I sat on a chair in my bathtub because I felt so dirty from not being able to take a shower. So I would sit there in the bathtub in a chair and let the water run on me, just to get a shower to keep clean.

Six weeks later, I went in to my doctor, begging him to let me go back to work because I was going nuts. I had cabin fever. I was not used to being condemned to a bed or anything else. I am a person who has always taken care of myself, and if there is something I want out there, I have gone for it myself.

I went back to work. Work was not easy. I worked in a major hotel in Seattle, and there was a lot of heavy work involved.

I then ended up having a suture infection. There are sutures in the muscle area that are left in there permanently. That became infected. I had to go in, and they had to open that up and take that one out.

I then continuously started having bladder and kidney infections for months to come, never having a problem with them before. Then I started having problems with ovarian cysts, never having had a problem before—and I will tell you, they are quite painful.

I had a problem with a blood clot to what they called the "bleeder". That had to be drained, and so far I have been lucky enough to have no more problem with that.

Every day, I walk out in society, seeing women pregnant, carrying babies, and knowing I cannot have that. I am now scared to death for every woman in this country because of my own experience. I fear to see it happen to them. It is no fun, and it is scary.

And now, to become a mother, I have to prove myself to a foster agency first is the way I have planned, because I wanted to start having children at the age of five. Well, with a lot of help, through my family and friends, I am going to do everything I can to become that foster mother, because I believe those children need me as much as I need them. The next step is to adopt, and it is not an easy one, and it is not an inexpensive one, either. I pray to God that that day comes for me, but I also pray to God that something can be done about this problem so another person does not have to go through it, or possibly lose their life.

I thank you for your time, and I hope that we can get something accomplished.

Senator ADAMS. Thank you, Barbara.

Barbara, if you could send a message to other women in the country today, what would you say, just in your own words?

Ms. ARBUCKLE. I would say if they have experienced any of the problems I just described; if they go in and have a test done, the Wall Street Journal put out an excellent article that gave a beautiful list of questions to ask your doctor.

Ask them if they are involved in the lab; if they have financial interest in the lab; if they know of this lab taking slides home; if they know of this lab having lawsuits because of Pap smears; if there is anything they hear from their doctor that they do not like, find out of they can use another lab. If the doctor does not want to go that route, go to another doctor, get another opinion; do not be scared.

We all do not want to hear that we have something wrong, but in the long run, we don't want to die, either. The questions may be hard to ask because of the fear of the answers, but ask them.

Senator ADAMS. Thank you, Barbara.

Without objection, I will put into the record the article that you refer to. I just think it is essential that those questions start to be asked and that both the medical profession and those that are running the laboratories be put on notice that the women of America are going to ask those questions.

[Information supplied follows:]

THE WALL STREET JOURNAL MONDAY, NOVEMBER 2, 1987

Lax Laboratories

The Pap Test Misses Much Cervical Cancer Through Labs' Errors

Cut-Rate 'Pap Mills' Process Slides Using Screeners With Incentives to Rush

Misplaced Sense of Security?

By WALT BOGDANICH
Staff Reporter of THE WALL STREET JOURNAL

The Pap smear. Over the past three decades, it has sharply reduced deaths from cervical cancer. Women and physicians trust it, so much so that the Pap smear has become one of the most common laboratory tests in America.

It is also one of the most inaccurate. No one knows how many women die because a lab botches the analysis or a doctor takes an inadequate specimen. The test, as it is being done today, fails to detect roughly one in every four cases of cancer or precursor cell abnormalities.

Linda MacNeil was one victim. A Florida store manager, Mrs. MacNeil suspected cervical cancer after experiencing bleeding, but a Pap-test report reassured her. Four months later, another test found cancer. Mrs. MacNeil died at age 36.

Cindy Gray's Pap smear wasn't analyzed in a laboratory at all but in the home of a lab employee, in violation of a federal regulation. There was no supervision and no pathologist to consult. Although the test reported no malignancy, the North Carolina mother of three was found soon after to have cervical cancer. She died at 34.

Barbara Arbuckle, of Seattle, was luckier. She is still alive. The 25-year-old woman received negative Pap-test reports, from two different labs, in the months before finding out she had invasive cervical cancer.

Incentives to Hurry

To find out why the Pap test falls so short of its promise, this newspaper visited labs, inspected records and interviewed doctors, lab workers and government officials. What emerges is a picture of a Pap-screening industry kept afloat by overworked, undersupervised, poorly paid technicians. It is an industry that often ignores what few laws exist to protect women from slipshod testing.

Across the nation, high-volume, cut-rate laboratories, sometimes called Pap factories or Pap mills, allow technicians to analyze up to four times as many specimens per year as medical experts recommend for accuracy. Many of them pay screeners on a piecework basis that encourages them to rush the analysis.

Some technicians work two or more jobs, earning as little as 45 cents to do the key analysis on a test that may cost the patient $35. In some cases, they say they are penalized if they resist the pressure to screen more slides in a day.

Work at Home

"I think women would be horrified to learn what's happening out there," says Dwight Golann, former chief of consumer protection for the Massachusetts attorney general's office.

Women and their doctors might be surprised to learn that labs often let employees take slides home to screen. "That borders on fraud," says Myron R. Melamed, a physician at Memorial Sloan-Kettering Cancer Center in New York.

Pap mills prosper by underbidding competing labs, charging as little as $1.50 per test. They are sought out by some gynecologists, who profit by marking up lab fees on patient bills.

Cost Pressure

But their bargain rates also appeal to budget-conscious administrators of group health plans and government-funded clinics. Thus, at a time when pressures are great to restrain medical expenses, problems with Pap-testing accuracy exemplify the possible trade-off in quality of care.

The consequences of faulty testing pose disturbing questions for the medical establishment. An estimated 60,000 women this year are expected to develop cancer of the cervix. If caught early, the disease is nearly always curable. Yet it kills about 7,000 American women a year.

"It is time for the medical community to acknowledge the failures of cervical cancer screening in the U.S.," says Robert Hasselbrack, a pathologist who runs a clinical laboratory in Seattle. Another physician, San Francisco pathologist Eileen King, complains: "Women have been told for many years that a Pap smear will tell them when they have cancer and when they don't. That is a big falsity."

Heightening the urgency is the fact that some doctors now believe cervical cancer develops faster than previously believed. Also, they see it turning up in more young women.

Citing an "alarming number" of cervical-cancer cases in women with recent negative Pap smears, the American College of Obstetricians and Gynecologists has criticized the American Cancer Society for advising women that they need a Pap test only every three years after two consecutive negative annual tests.

"Nothing merits total faith, but nobody can doubt its [the Pap test's] value," says Robert Hutter, a physician who is a past president of the society. Still, the society is considering recommending that women take the test more frequently.

Leading cancer specialists say about half the Pap-test failures result because physicians take inadequate cell samples. But efforts to better educate doctors in taking specimens have been "spectacularly unsuccessful," says the obstetrician and gynecologist association.

Labs could help by rejecting inadequate slides sent to them. But "even good labs" are reluctant to do so, for fear of losing business, says Dr. S.B. Gusberg, another past president of the American Cancer Society.

Wallpaper Challenge

The Pap test is named for George Papanicolaou, who developed it in the 1920s. To prepare a specimen for the test, a doctor smears cells from the female genital tract onto a glass slide, in some cases two slides. Most aren't analyzed by a doctor but by a cytotechnologist, who ordinarily is a college graduate with a year of special training. Unlike some kinds of medical tests, Pap smears aren't checked by chemical or mechanical means but depend on human visual examination of the specimen.

A slide may contain hundreds of individual cells, each of which should be studied under a microscope. It is tedious work and, if done properly, time-consuming. Louise Newton, an Albany, N.Y., "cytotech," likens the job to examining wall after wall of flowered wallpaper.

"Imagine trying to look at every flower and see how buggy you get," she says. "Tired eyes make mistakes."

Accordingly, the American Society of Cytology recommends that no full-time cytotech examine slides from more than 12,000 patients a year. A 1980 conference of cancer specialists convened by the National Cancer Institute also supported this limit. But it is flagrantly ignored.

Workload Controversy

An analysis by this newspaper of government data found that more than half of the Pap smears sent to New York state-regulated labs are screened in places where technicians exceed the recommended workload. Kyto Diagnostics Inc. of New City, N.Y., a large private lab run by a prominent cytopathologist, Ralph Richart, reported average workloads of 35,000 cases per screener last year—nearly three times what the cytology society thinks is safe. Most of his screeners aren't even full-timers.

Dr. Richart and other critics of workload limits say some cytotechs can accurately screen more than others. They argue that those who make excessive errors will be caught if a lab randomly rescreens at least 10% of negative slides.

Other medical experts disagree. Because only a small percentage of slides are likely to be positive, they say, and because everyone makes some errors, finding a problem employee might take years using a random 10% rescreen. "It's a seriously flawed quality-control technique," concludes Robert R. Rickert, vice chairman of lab accreditation for the College of American Pathologists.

Even as Pap-smear volume is rising, the number of qualified screeners is shrinking. Fewer people are choosing the field, and many are leaving it for better pay. Nearly half the schools that train cytotechs have closed in recent years; hospitals no longer find them economic to run.

"It is approaching a crisis," says San Francisco's Dr. King, who is studying the problem on behalf of California pathologists. Nearly 50% of advertised positions for cytotechs in California remain unfilled, she has found. Paul Krieger, director of anatomic pathology for MetPath Inc., a laboratory unit of Corning Glass Works, says that if the American Cancer Society decides to recommend more frequent Pap testing, "I don't know how we or anyone else is going to handle it."

To cope with the labor squeeze and to lower their costs, labs are turning increasingly to piecework, promising cytotechs that the more slides they screen, the more they will earn. Nowhere else in laboratory medicine is this method of payment so prevalent. "It's very bad practice. It makes quality control difficult," says Dr. Melamed of Sloan-Kettering.

Some big commercial labs pay almost exclusively by piecework, avoiding many employee costs. Even labs with salaried cytotechs, such as MetPath, usually let them do extras on a piecework basis.

Karen Sanford, a cytotech in Stockton, Calif., left a high-pressure piecework lab in the Los Angeles area after learning from a patient's doctor that she had failed to catch some abnormalities. "It really freaks you out," she says. "What do you say? It happened to me twice. That's when I decided to get out of there."

Not everyone is so conscientious. A particularly dangerous, yet very common, practice among cytotechs is to piggyback Pap-smear screening jobs, doing the maximum allowed at one lab, then meeting another lab's quota later in the day.

Midnight Oil

"Over 50% of the people I know have two jobs. Some have three or four," says Jason Betterton, a cytotech in Sylmar, Calif. Ms. Sanford tells of a technician who screens at three labs, working from 1 a.m. until late the next afternoon.

Labs frequently let workers leave for the day as soon as they reach their quotas—another incentive to screen slides as rapidly as possible. Lon Barr, a cytotech in Poway, Calif., says that when he joined a San Diego Pap lab he was "astonished" to see workers screen 100 slides in 3½ hours, then leave. "It was inconceivable that someone could screen that fast," he says.

Dr. Hasselbrack, the Seattle lab owner, says that in Pap mills, screeners lose sight of the fact that "you are looking at somebody's life, and if you make a mistake, it may be all over."

Piecework pay scales also encourage overwork. At 50 cents a slide, one who stuck to the cytology society's workload limit would earn only $6,000 a year.

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Lax Laboratories:

Little Regulation

Only one state, California—even attempts to prevent workload abuses. Its law states that "no cytotechnologist shall be required to examine more than 75 one-slide gynecologic cases, or 50 two-slide gynecologic cases per day."

But labs often violate or skirt this law. Start with the biggest Pap lab in the country, Cancer Screening Services, of North Hollywood. Almost a million Pap cases were processed last year by this unit of American Cytogenetics Inc. (which a West Coast business magazine in 1985 dubbed California's hottest stock).

Cancer Screening's full-time employees are required to do 100 slides a day, says Shahla B. Sadeghi, medical director. It has mostly one-slide cases. Reminded of the state's legal limit, Dr. Sadeghi says: "It's not really a law—they just suggest it. . . . They know it's not possible." She adds, "Every year we have passed the [state] inspection."

At Central Diagnostic Laboratory in Tarzana, Calif., says former employee Betty Jo Thompson, "there was no such thing as you couldn't do your 100 cases." Moreover, screeners were expected to do extras at $1 a slide, she says. California law lets workers analyze an unlimited number of Pap smears a day if they "volunteer," but Mrs. Thompson says that when she resisted doing extras, the lab cut her salary.

Cyrus Milani, a Central Diagnostic medical director, says workers are sometimes required to do 100 cases daily. He declines to be interviewed further, except to state that the lab does quality work. Another company official denies that the lab violates any laws.

At Yosemite Pathology in Modesto, "100 slides is what we consider the minimum," says spokesman Robert Colletti. He doesn't feel he is violating the law because "everybody interprets it differently."

Few Proficiency Tests

Stephanie Harner, past president of the California Association of Cytotechnologists, says she has complained repeatedly to state health officials about pressures on cytotechs to exceed quotas, but "got mostly a non-response." Kenneth Kizer, director of California's health department, denies that his office has received complaints from cytotechs. He promises to investigate.

The federal government doesn't care about workload or piecework issues. It does prohibit labs under its jurisdiction from letting "kitchen cytologists" analyze Pap tests at home, but many do so anyhow. At the home, pathologists aren't available for consultation, and no one checks how carefully slides are examined. "Cytology is done in so many nooks and crannies—places we don't even know of," says Susan Yokota, a cytotech.

Cancer Screening Service, for example, is federally certified as an interstate lab, yet it concedes that workers in the past took slides home. The company says that happened only a few times and is no longer permitted. A Tulsa, Okla., laboratory permitted home screening of smears from government financed clinics until a Journal reporter began inquiring about the practice.

The only equipment needed for Pap screening is a microscope. But as one lab worker points out, "It's not something to do after a day's work in between washing dishes, with kids screaming for attention."

Patients believe the government is watching over Pap testing, says Lawrence Bergner, a physician at the National Cancer Institute, "but it ain't so." The government sets some standards for interstate and Medicare-certified labs, but the Pap test is the only common lab procedure for which federally licensed labs needn't undergo periodic proficiency tests.

As for the states, only one, New York, requires screeners to pass such tests.

Doctors seeking quality work often turn to professional groups that evaluate and accredit labs. However, the largest group overseeing commercial labs, the College of American Pathologists, doesn't set any overall workload limit. The American Society of Cytology, which does, has certified only about 40 of the more than 1,000 labs analyzing Pap smears nationwide. Many of the largest labs have never sought accreditation.

With weak laws and scant professional oversight, there is little to protect women from the kinds of misfortunes suffered by Mrs. MacNeil, Mrs. Gray and Ms. Arbuckle. In all three instances, their Pap slides were misread, according to testimony in lawsuits filed in their state courts. Ms. Arbuckle's suit is pending; survivors of the other two women received large monetary settlements.

Elusive Slides

It often is impossible, however, to determine what went wrong—whether the specimen was misread by the lab or whether, perhaps, it was poorly taken by the doctor. Pap slides are often kept only as long as the law requires. In states without laboratory laws—which is nearly half of them—a lab needn't keep slides at all unless it operates in interstate commerce or is Medicare-certified. In that case, it must keep them two years.

Patricia Ashton, a cytotech and consultant to a major national laboratory, says that her lab's lawyers instruct workers to "get rid of slides as soon as possible" to limit liability. "I don't think its medically ethical," she says.

Even if a suspect slide exists, retrieving it can be a problem. A now-defunct Boston laboratory called Elm Medical Lab, after having failed to detect a woman's cervical cancer, covered up the error by substituting a negative Pap slide for a positive one in her file, according to evidence presented by the Massachusetts attorney general in a state court. A jury last year found the lab had violated state consumer-protection laws; the case is on appeal.

Mr. Golann, who handled the state's case, also presented evidence that slides were improperly prepared at the lab, that one screener spent just seconds on each specimen; that slides were examined at home; and that the lab had failed to find the abnormal cells on 10 of the first 12 positive slides checked by investigators in a rescreening.

The dimensions of some abuses have been stunning. A Mansfield, Ohio, lab in the late 1970s was discovered to have sent out nearly 6,000 erroneous Pap-test reports. A world-wide alert located many, but not all, of the women affected. And this past September, health authorities in Britain issued an international alert for 911 women who had Pap smears misdiagnosed by a leading pathologist there.

Planned Parenthood

Bad lab work is currently a paramount concern for Planned Parenthood Federation of America, which last year took 1.4 million Pap smears through affiliated offices and clinics. Early this year, Planned Parenthood warned affiliates of "a rapid rise in the number and cost of claims" due to laboratory errors, specifically Pap smears.

A few years ago, it tried to catch a lab it suspected of misreading Pap slides. Twice it sent the lab, which it won't name, slides from women known to have cervical cancer or its precursors, and twice the lab failed to report abnormalities. When Planned Parenthood tried to retrieve the specimens, one set was said to be lost and the other came back smashed. It was as if "they beat them up with a hammer," recalls Louise Tyrer, a physician who is vice president for medical affairs.

With complaints about lab work pouring in, Planned Parenthood has begun trying to identify problem Pap labs. One lab that has come to its attention is International Cancer Screening Laboratories in San Antonio, Texas. Among the largest in the nation, ICSL processes about a half-million slides annually from 49 states. In 1985, it was banned from operating in New York after failing the state's proficiency test in cancer screening.

ICSL, operating out of a modern building on the outskirts of San Antonio, employs 42 screeners full or part time. It pays the part-timers 50 cents a slide and gives salaried employees 45 cents for each slide they screen after meeting the daily quota.

Big Producer

One screener is recorded as having analyzed 4,710 slides in June. That is a rate more than four times what the American Society of Cytology considers the maximum safe workload. Even if he worked all 30 days in June, the screener would have to have done 157 slides a day.

At such rates, "I wouldn't expect a cytotech to screen effectively or reliably," says George H. Anderson, a physician at the Cancer Control Agency of Vancouver, British Columbia, which has a highly regarded Pap screening program. Says Dr. Hutter of the American Cancer Society: "If such things are happening, then I would say that's terrible."

ICSL's president, Robert Boughton Jr., says that his lab's work "is the best humanly possible," and that he spends more money than other labs do on quality control. He also says the especially prolific screener's error rate is well within acceptable ranges.

But in a business where one mistake can have tragic consequences, the technician, who declined to be interviewed, last year made at least 93 errors—41 of them "major," lab records show. And those are just the ones uncovered in a routine rescreening of 18% to 20% of his negative slides. No one knows his actual error total.

Mr. Boughton attacks workload limits as the creation of physicians who "sit up in their ivory tower with a bottle of wine" and issue pronouncements. Lending authority to his attacks on workload limits is a Ph.D. degree he says he earned in biology from the University of Mexico in Monterrey "in 1981 or 1982." He is identified in state and federal regulatory records as having a doctorate.

The University of Mexico, however, doesn't have a branch in Monterrey. And no record of Mr. Boughton's Ph.D. could be found at two other universities in that city. Mr. Boughton declines to provide a copy of the diploma, saying, "I am telling you that I have it, and that is all I have to say."

Present and past screeners, who ask not to be identified, say that despite ICSL's huge volume, its medical director works only part time. They also say that 10% or more of the slides sent to the lab are broken in transit. "You could easily miss an abnormality on the broken spot," says one ICSL cytotechnician.

Mr. Boughton says the breakage rate is "5% to 7% at the most." He says that while his medical director holds another job with a state mental hospital, she puts in nearly full-time hours at ICSL. He also makes no secret of the fact that he continues to operate in New York state, even though it banned his lab in 1985 after it

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failed the cancer-screening proficiency test. "Who's going to stop me?" he asks.

A spokesman for the state, Mary Anne Gardineer, says, "If we can verify that [ICSL] is accepting samples from New York state, we will stop them."

Amid growing criticism of laboratory work, the American Society for Cytotechnologists is pressing for tough government workload limits—even though they would reduce many screeners' pay. "Just as the public needs protection from fatigued truck drivers," the society says, "it needs protection against life-threatening mistakes in the laboratory by overburdened personnel."

Meanwhile, the society has begun a campaign to urge women to ask their doctors where their Pap smears are analyzed. At the very least, women should be told that their Pap test may fail to detect abnormalities, many health experts say. This way, women may be less likely to skip their next gynecologic exam.

Failure Rate

The American College of Obstetricians and Gynecologists, citing studies of hundreds of women, puts the Pap test's "false-negative" rate—the failure to reveal or report abnormalities—at 20% to 40%.

The Pap test's reliability compares unfavorably with that of other lab tests. Drug tests, for example, have been criticized as being inaccurate. But labs measured in a nationwide proficiency test last year had a much lower false-negative rate of about 5%. Even under the best of circumstances, says Dr. Anderson of Vancouver, a Pap test will have a false-negative rate of at least 10%.

To help bring error rates down, San Francisco's Dr. King argues for better pay and working conditions for cytotechs. "The field has become unattractive to intelligent, dedicated people of the kind we have always had," she says.

Above all, people in the field don't want Pap testing to remain laboratory medicine's errant stepchild. They prefer to think of it as a test so important that a commemorative stamp was issued in its name in 1978. At the White House ceremony marking the event, Postmaster General William Bolger said of Dr. Papanicolaou: "He wanted to eradicate those awful words so many doctors have quietly voiced: 'If only we had known sooner.'"

Mrs. Gray, the North Carolina woman who got a negative Pap-test report before finding she had cervical cancer, felt the tragic sting of that lament. After the cancer had spread through her body, she underwent several operations, chemotherapy and radiation. As part of a lawsuit, Mrs. Gray gave a videotaped deposition from her sickbed, describing in detail the agony of her struggle for life. The deposition ended with her vow: "I made some plans to beat this thing."

Two months later, Cindy Gray died.

Women May Want to Ask Who'll Screen a Pap Test

Women concerned about Pap-test accuracy might consider asking their doctors questions such as these:

—What is the name of the lab, and is it accredited by a professional group? (Accreditation offers no guarantee, but at least it means someone is looking over the lab's shoulder.)

—What are workload levels at the lab? Are screeners salaried or paid on a piecework basis?

—Can I get a copy of the lab report? (Don't assume that if you don't hear from the doctor the test must have been negative. There are such things as mix-ups, oversights and lost reports.)

—Is the lab nearby? (If a doctor sends the specimen to a lab far away, he should have a good reason.)

In Oklahoma, a Different Lab to Screen Pap Tests Means Very Different Results

By Walt Bogdanich

Staff Reporter of The Wall Street Journal

OKLAHOMA CITY, Okla.—Legislators can attest that women in this state take cancer screening seriously. When lawmakers in the late 1970s voted not to finance a free Pap smear program, women protested at the state capital with such vigor that the legislators backpedaled.

The women's victory, it turns out, may have been hollow. Intent on reducing the program's cost, the state health department in mid-1986 stopped sending Pap smears to be analyzed by its longtime contractor and began awarding one-year contracts to the lowest bidder.

Now, Adeline Yerkes, a state health official, says it is possible that hundreds of Oklahoma women are walking around with undiagnosed precancerous conditions because of misreported Pap-test results. The low-bid lab reported far fewer "abnormals" than did its predecessor, Oklahoma Teaching Hospitals.

For years, "abnormals" consistently came in at 7% to 9% of the total Pap smears analyzed each year, including a 9% rate in the year ended in June 1986. In the following 12 months, the new contractor, Northwest Laboratories Inc. in Oklahoma City, reported only about 3.5% abnormals, says Mrs. Yerkes, the head of the state program.

The figures suggest that Oklahoma officials "have something to worry about," says Lawrence Bergner, a physician at the National Cancer Institute. "They should really examine it."

But whether the results are misdiagnoses or statistical glitches won't be known for some time, if ever. Four months after the contract ended, the state still hadn't rescreened any significant number of slides to determine their accuracy. Mrs. Yerkes says it can afford to rescreen only 250 of the nearly 100,000 Pap smears. And it is still searching for someone to rescreen just these 250.

She hasn't alerted women to the possible misdiagnoses. Any missed abnormalities, she explains, will be caught when the women show up for their next exam. Mrs. Yerkes says there is no need for panic, because cervical cancer develops slowly.

The state concedes, however, that women may move and be unreachable, or may neglect their next appointment. In addition, there is evidence that cervical cancer in some women develops much faster than previously believed.

"I think it's disgusting," says Dana Dye, who teaches cytotechnology—the screening of cell specimens—at the University of Oklahoma Health Sciences Center. "If she has any doubt, she should let somebody go over those slides."

Northwest Laboratories, which declined to be interviewed, won the contract for the 12 months in question with a bid of $1.50 a slide. The bid from Oklahoma Teaching Hospitals, the old contractor, was more than twice that.

But the state didn't follow up on who actually did the screening. Northwest, it turns out, was so understaffed that it farmed out some of the work. It loaded hundreds of Pap-smear slides into a car and drove them to a cut-rate laboratory in Texas.

Mrs. Yerkes says Northwest's staffing problems became apparent early in the contract, with some screeners carrying excessive workloads. That was soon corrected, she says. But the contract lab was late delivering results, and seemed to have high screener turnover. "The quality of the reading wasn't up to our standards," she says.

The state has contracted with a different lab for the 12 months that began July 1 and has written staffing safeguards into the contract, Mrs. Yerkes says. But when a reporter examined the contract on file in the state capital, the safeguards weren't there. "I don't know what happened," Mrs. Yerkes says.

She says she inspected the lab that holds the new contract, Jerry L. Puls M.D. Inc. in Tulsa. "I know they have an adequate staff," she says. "All Paps are being screened in Tulsa in his own lab."

However, this newspaper learned that many slides the state sent to the new contractor weren't being screened in a laboratory at all but rather were taken home by unsupervised technicians, in violation of federal regulations for Medicare-certified labs. Dr. Puls was told of the discovery and now says he has stopped the practice.

Jack Painter, the manager of the anatomic pathology laboratory at Oklahoma Teaching Hospitals, says that previous screening programs cut the number of deaths from cervical cancer and that now he fears death rates may go back up. But, says Betty McClellan, a pathologist in his laboratory: "Unfortunately, I think it will take years before the mistakes, if any, become apparent."

Senator ADAMS. I would ask you the same thing, Ms. Thompson.

Ms. THOMPSON. I think the most important thing is a second opinion. And I must tell you as a woman—and I think any woman in this room will tell you that to have a Pap smear done is humiliating, embarrassing; it hurts. And most of us do not want to do it. So to tell women to get a second opinion is asking them to do an awful lot.

But if you feel that something is wrong with your body, I am totally convinced after having spent the time that we have on this story, you have to get a second opinion to save your life, because I know how frail this test is. I know how frail it is from a doctor's perspective, and I know how frail it is from a cytotechnologist's perspective. And I think you cannot assume that your doctor has taken the test right, and I certainly do not think you can assume that the cytotechnologist has read it right.

So if something is wrong—and I think Barbara Arbuckle told you about the symptoms—if something does not seem right, you just have to go and get another Pap smear, and ask your doctor where it is going.

I must tell you, very early on when we started working on the story, I called my ob-gyn and I said, "Where do you send Pap smears?"

And he said, "Nobody ever asks me that."

I can give you a few rules-of-thumb that we believe are true. We think hospital laboratories do better work than commercial laboratories.

I think you need to ask whether the hospital is Medicare-inspected and regulated, because we know in our area, and we know throughout the country, that many labs are not inspected and regulated.

I think you need to ask your doctor for your medical test and look at it, and you probably won't understand it, but ask him what it means. And if it takes a little more of his time, well, too bad.

Senator ADAMS. Thank you both very much.

Senator Mikulski.

Senator MIKULSKI. Thank you very much, Senator Adams.

To you, Ms. Arbuckle, thank you for that eloquent testimony. I know it was very hard for you to go through this in front of us all, and we thank you for your courage in coming forth and making yourself available.

Lea, I would like to talk with you a minute or two. First of all, again, many thanks for this series. And as we look at the big national picture, Medicare labs, and so on, I like to get a sense of these things in terms of Maryland, our home State.

I noticed you talked to one of the physicians in the Maryland State Health Department. My question to you is what did Maryland tell you, and what did your investigation about Maryland tell you about laboratory safety and laboratory reliability and certification and professional qualifications of the lab techs?

Ms. THOMPSON. Do you want me to speak specifically to Pap smears?

Senator MIKULSKI. Yes, only to Pap smears.

Ms. THOMPSON. In the case of Pap smears, the State of Maryland does not in any way require certification or regulation of those cytotechnologists who do Pap smears. They are not in any way independently tested to make sure they know what they are doing.

Senator MIKULSKI. So it could be someone from a very fine college with exceptional training, or it could be a medical secretary.

Ms. THOMPSON. Well, it probably would not be a medical secretary, in that Pap smears are too difficult for a secretary to read, unlike other tests that are being read by secretaries. But there is no reason to believe that the cytotechnologists that are doing the work in Maryland laboratories know what they are doing, because nobody ever tests them to make sure they do know what they are doing.

You are going to hear from Dr. Herb Dickerman, who is going to tell you how it can be done. I found it incredible that the only State in the United States of America that is testing the techs who do this work is the State of New York. I think Dr. Dickerman will tell you that it is very feasible, it is very possible. It is not inexpensive. But if you consider the consequences, I am convinced that cytotechs have to be tested; I am.

Senator MIKULSKI. And what else did you find out about the Maryland labs? Are they inspected? Is the technology tested?

Ms. THOMPSON. It depends on which kind of laboratory you are talking about. Hospital laboratories are inspected and regulated; commercial laboratories in Maryland are inspected and regulated. Doctors' laboratories are just beginning to be looked at. When we did our story, 80 doctors' labs had been looked at and had been inspected.

But there are massive loopholes in the Maryland law in that regard. In order to be inspected in a doctor's office, you have to have four or more doctors who are practicing and own the practice together, which gets rid of all kinds of corporate-owned clinics, HMOs, and any doctor's office that is less than four people. So it is pretty easy to get out of the Maryland law.

Senator MIKULSKI. Well, thank you. You know, we women spend a lot of our own energy and our own money trying to protect ourselves from cancer. Now, we find that we have to protect ourselves against the labs who are supposed to find out if we have cancer.

Maryland has, unfortunately, in the last couple of years, a lackluster approach to regulation. We all know about the S&L crisis because we did not have inspectors on the job. I think we can do better in my own home State, and I can tell you as a result of your investigation, while Senator Adams and I will be working on the national picture, I intend to contact Governor Schaefer, who I know to be a good man and a very concerned man, about directly taking on the issue in Maryland to see if we can do the certification testing, the reliability testing, and at least make sure there will be not only one State, but at least two States in the United States that do the right thing.

Thank you for your comments.

Ms. THOMPSON. Senator, I do want to tell you that the State of Maryland is by far not the worst State when it comes to laboratory inspection and regulation. In fact, it is better than most States. There are things that can be done. I think in our area, we certainly need to look to the South, where Virginia has done absolutely nothing.

Senator MIKULSKI. Well, I am from Maryland, so we'll start there.

Senator ADAMS. Barbara, I can assure you we will do the same thing in the State of Washington, and we are going to have Dr. Hasselbrack here to talk about that. I will talk with the Governor.

I am also concerned about the evidence we have, which I think we are going to hear more of, of the practice of shipping to cut-rate interstate labs where you have in effect sweatshop conditions for cytotechnologists. That is also part of it.

So you have done the public a great service. It was hard for you, and I want you to know we understand that, and we appreciate it more than I can tell you. So thank you.

Ms. ARBUCKLE. Thank you.

Senator ADAMS. Thank you both very much.

Our second panel will be Dr. Cyril Schulman, Clinical Professor of Medicine at George Washington University, representing the American Cancer Society; Dr. Robert Hasselbrack, Director of the Fifth Avenue Medical Center, Accu-Pap Diagnostic Services, Seattle, Washington; Ms. Patricia Ashton, President of Cell Diagnostics, Inc., Durham, North Carolina, representing the American Society for Cytotechnology; and Dr. Herbert Dickerman, Director of the Wadsworth Center for Laboratories and Research, New York State Department of Health, Albany, New York. If you would please all come forward, we would be prepared to hear your testimony.

I might also indicate that the minority portion of the committee has requested that we hold a minority day of hearings. I am most pleased to support such a request, and that will occur, also.

I want to welcome all of you. We appreciate your coming before the Committee today. Many of you have already been referred to in previous testimony. You are known experts. We need your help, we want it, and we appreciate it.

Dr. Schulman, why don't we start with you, simply because you are at this portion of the table. We will reserve questioning until all of you have had an opportunity to make an opening statement, and then we will proceed with questions.

Dr. Schulman?

STATEMENTS OF DR. CYRIL A. SCHULMAN, CLINICAL PROFESSOR OF MEDICINE, GEORGE WASHINGTON UNIVERSITY, WASHINGTON, DC, ON BEHALF OF THE AMERICAN CANCER SOCIETY; DR. ROBERT HASSELBRACK, DIRECTOR, FIFTH AVENUE MEDICAL CENTER, ACCU-PAP DIAGNOSTIC SERVICES, SEATTLE, WA; PATRICIA ASHTON, PRESIDENT, CELL DIAGNOSTICS, INC., DURHAM, NC, ON BEHALF OF THE AMERICAN SOCIETY FOR CYTOTECHNOLOGY; AND DR. HERBERT DICKERMAN, DIRECTOR, WADSWORTH CENTER FOR LABORATORIES AND RESEARCH, NEW YORK STATE DEPARTMENT OF HEALTH, ALBANY, NY

Dr. SCHULMAN. Thank you very much, Mr. Chairman and Members of the Committee.

I am very pleased to be here today to discuss the importance of routine Pap tests in the early detection of cancer of the uterine cervix.

I am Dr. Cyril Schulman. I am a clinical professor of medicine at George Washington University School of Medicine. I am a member of the National Board of Directors of the American Cancer Society, and I am also a past President of the District of Columbia Division of the Cancer Society.

You have just heard testimony from medical experts and from a courageous cancer survivor—several of them, if you include the breast—about the importance of early detection in saving lives and improving the quality of life for breast cancer patients.

Now, like the mammogram, the Pap test is highly effective in the very, very early detection of cancer of the cervix and its cure. In fact, the Pap test has been the major reason for a reduction in the mortality rate for cervical cancer by more than 70 percent over the past 40 years.

According to the American Cancer Society's 1988 Cancer Facts and Figures, there will be almost 13,000 new invasive cases of cervical cancer in 1988, and an estimated 7,000 deaths—primarily in patients who have not had Pap tests, however.

The most common symptom of cervical cancer is abnormal vaginal bleeding, or an increase in vaginal discharge. While these do not mean cancer, they do mean a pelvic examination and a Pap smear is absolutely necessary.

Unfortunately, many women with cervical cancer or its precursors do not exhibit any symptoms prior to detection. What, then, is the best way to detect the disease?

Regular pelvic examination and Pap smears are the very best way to detect cervical cancer and pre-cancerous conditions early. During the examination, the physician will check all of the organs in the pelvic area.

Now, the Pap test consists of a scraping of the cervix and thus the collection of a sample of cells which are smeared on a slide. These are then examined under a microscope. If the doctor suspects, or a Pap test shows some abnormality, a biopsy is usually done to obtain tissue for microscope examination and further tests.

The Pap test very occasionally fails to pick up cancer cells for a number of reasons. The possibility of such false negative results is one reason why women should have Pap tests and pelvic examinations on a regular basis.

Pap tests can detect dysplasia and cancer in situ, which are two symptom-free conditions that sometimes develop into invasive cervical cancer. Dysplasia, which is the development of abnormal cells by some secondary local infection and a number of other causes, is not a cancerous condition. Cancer in situ is cancer, but it is in its very earliest stage. Both conditions are essentially 100 percent curable.

Recent research indicates that one type of virus, the human Papilloma virus, plays a role in the development of cancer of the cervix and the transformation of dysplasia into cancer.

Because of confusing guidelines, in August 1987, the American Cancer Society sponsored a workshop to examine a series of issues related to the benefits of the Pap test and to draft a series of consensus guidelines. In attendance were representatives of many health and professional organizations who agreed to a series of guidelines. The American Cancer Society's Board of Directors approved the following guidelines in November 1987—and I quote—"that all women who are or have been sexually active or have reached the age of 18 years have an annual Pap test and pelvic examination. After a woman has had three or more consecutive satisfactory, normal annual examinations, the Pap test may be performed less frequently at the discretion of her physician."

The American Medical Association, the American College of Obstetricians and Gynecologists, the National Cancer Institute, the American Academy of Family Practitioners, the American Medical Women's Association, and the American Nurses Association are among those organizations who have adopted these guidelines.

The actions of these organizations reaffirm the critical importance of Pap screening. There have been recent media reports of high percentage of negative results and violations of professional standards by some laboratories used to interpret Pap smears. However, it would be tragic if women rejected the Pap test because of confusion, complacency, or even cynicism about the Pap test.

The overriding fact is that the Pap test finds very early cervical cancer, and perhaps more importantly, the simple, painless and inexpensive test finds even precancerous conditions which are easily treated.

Treatment of middle-and late-stage cervical cancer markedly increases medical costs, which in turn impacts on the Federal government if the patient is enrolled under Medicare or Medicaid, and on private health insurance companies.

Survival rates for patients in late disease stages drop tremendously. We have the ability to change that, and I believe we have that responsibility.

In closing, Mr. Chairman, I commend the Committee for holding this hearing, and urge you to take steps to make proven cancer detection procedures available to all Americans. I am talking about the Pap test and the mammogram, both of which are excellent methods for detecting early cancer.

Thank you, Senator.

[The prepared statement of Dr. Schulman follows:]

AMERICAN
CANCER
SOCIETY

TESTIMONY OF

CYRIL A. SCHULMAN, M.D., F.A.C.P.

CLINICAL PROFESSOR OF MEDICINE
GEORGE WASHINGTON UNIVERSITY SHCOOL OF MEDICINE

WASHINGTON, D.C.

REPRESENTING THE

AMERICAN CANCER SOCIETY

"CANCER DETECTION IN WOMEN"

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

JANUARY 28, 1988

For more information please contact:
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Mr. Chairman, and Members of the Committee. I am pleased to be here today to discuss the importance of the Pap test in the early detection of cancer of the uterine cervix.

I am Dr. Cyril Schulman, Clinical Professor of Medicine at George Washington University School of Medicine. I am a member of the National Board of Directors of the American Cancer Society, and am a past president of the District of Columbia Division of the Society.

You have just heard testimony from medical experts and from two courageous cancer survivors about the importance of early detection in saving lives and improving quality of life for breast cancer patients. Like the mammogram, the Pap test is highly effective in the early detection of cancer -- cancer of the uterine cervix. Many studies have demonstrated the effectiveness of the Pap smear in screening for cervical cancer; well-screened populations show a dramatic reduction in both the incidence and mortality of invasive cervical cancer. In fact, the Pap test has been primarily responsible for a reduction in the mortality rate for cervical cancer by more than 70% over the past 40 years.

According to the American Cancer Society's 1988 Cancer Facts and Figures, there will be approximately 12,900 new invasive cases of cervical cancer in 1988, and an estimated 7,000 deaths.

I must emphasize that the best chance of improving survival and reducing mortality from cervical cancer is by screening and earlier detection. By educating the medical profession and women about the importance of regular examinations including the Pap test, and, and by making the test available to the patient, cervical cancer could be caught at its earliest disease stage, and more lives could be saved each year.

The most common symptom of cervical cancer is abnormal vaginal bleeding, bleeding that starts and stops between regular menstrual periods or bleeding that occurs after intercourse or after a gynecological examination. An increased vaginal discharge is another common symptom. While these are not sure signs of cancer, they do indicate the need for further tests, including a complete pelvic examination and Pap smear. Unfortunately, many women with cervical cancer or its precursors do not exhibit symptoms prior to detection. What then, is the best way to detect the disease?

Regular pelvic examinations and Pap smears are the best way to detect cervical cancer and precancerous conditions early. During the examination, the physician will check all of the organs in the pelvic area, including the uterus, vagina, ovaries, fallopian tubes, bladder, and rectum. A speculum is used to hold the vagina open so that the physician can view the upper portion of the vagina and the opening of the cervix. A Pap test consists of the collection of a sample of cells (a smear) from the cervix and examination of these cells under a microscope. The Pap test sometimes fails to pick up cancer cells. The possibility of such "false negative" results is one reason why women should have Pap tests and pelvic exams regularly.

The Pap test can detect dysplasia and carcinoma in situ, two symptom-free conditions that sometimes develop into invasive cervical cancer. Both conditions are almost 100% curable if treated promptly. Dysplasia, the development of abnormal cells, is not a cancerous condition. Carcinoma in situ is cancer that has not spread below the lining of the first layer of cervical tissue. It is the earliest form of cervical cancer that can be detected, and is almost 100% curable.

Medical scientists have identified certain risk factors which may help women identify certain patterns in their lives which have been associated with higher incidence of cervical cancer. The incidence of cervical cancer is higher than average among women of low socioeconomic status, women who began having sexual intercourse at an early age, and women who have had many sex partners. As with many cancers, age is associated with increased risk for developing cervical cancer. Smoking does increase risk although scientists are unable to explain how this occurs biologically.

A number of factors suggest that cervical cancer is a sexually transmitted disease. Some studies have found increased levels of antibodies to genital herpes virus in some women with cervical cancer. Recent research indicates that another type of virus, the human papillomavirus, plays a role in the development of cervical cancer and the transformation of abnormal cells (dysplasia) into cancer.

Barrier contraceptives, such as a diaphragm or prophylactic protect against veneral infection, and may lessen risks associated with developing cervical cancer. The circumcision status of a sexual partner has not been found to increase cervical cancer risk.

Over the past eight years, many national and medical health organizations have developed differing guidelines for the use of the Pap test in the early detection of cervical cancer.

In August 1987, the American Cancer Society sponsored a workshop in Annapolis, Maryland to examine a series of issues relating to the benefits of the Pap test, its periodicity (frequency), and age of testing. In attendance were representatives of a number of national health organizations. At the conclusion of the meeting, participants agreed to bring the proposed consensus guidelines to their policy-making Boards or Councils. The American Cancer Society's Board of Directors approved the following guidelines on November 7, 1987:

> That all women who are, or have been sexually active, or have reached age 18 years, have an annual Pap test and

> pelvic examination. After a woman has had three or more consecutive satisfactory normal annual examinations, the Pap test may be performed less frequently at the discretion of her physician.

At least six other organizations have joined the American Cancer Society in modifying their guidelines so that they are similar or exactly like what the Society adopted. These organizations are the American Medical Association, the American College of Obstetricians and Gynecologists, the National Cancer Institute, the American Academy of Family Practitioners, the American Medical Women's Association, and the American Nurses Association. Other attendee organizations are in the process of reviewing the guidelines at this time. This is an historic show of cooperation on the part of health and professional organizations to reduce confusion among physicians, other health professionals, and women. It means that health professionals, especially physicians can give better counsel to their women patients.

The actions of these organizations reaffirms the critical importance of Pap screening. There have been recent media reports of high percentages of negative results and violations of professional standards by some laboratories used to interpret Pap smears. It would be tragic if women rejected the Pap test because of confusion, complacency, or even cynicism about the Pap test.

The overriding fact is that the Pap test finds early cervical cancer, and perhaps more importantly, this simple, painless and inexpensive test finds precancerous conditions which are easily treated. The eradication of precancerous lesions is virtually 100% effective in controlling or eliminating cervical cancer.

While young women have been the traditional target group for Pap testing, it is clear that mature women over age 65 years require testing as well. Testing mature women is critical if they do not have a history of regular Pap testing in their younger years.

Perhaps as many as 20% of American women are not reached through screening programs and account for a majority of the deaths, 7,000 in 1988, from cervical cancer. Health insurers, as a rule, do not cover routine, preventive-care exams, and the American Cancer Society believes this is shortsighted. The costs of making cancer detection procedures available to more women, through their health insurance programs, do not compare to the medical costs for treating advanced cancer. Saving lives, and preserving quality of life in cancer survivors must outweigh all other considerations.

In closing, Mr. Chairman, I would commend the Committee for examining issues related to cancer in women more closely. The American Cancer Society supports legislation that will provide for Medicare coverage of periodic health tests for the early detection of cancer. Thank you.

Senator **Adams**. Thank you, Dr. Schulman, for excellent testimony. We appreciate it.

Dr. Hasselbrack, welcome. We are very pleased to have you here. You are from my home city. We welcome you and look forward to your testimony.

Dr. **Hasselbrack**. Thank you very much, Senator Adams and Senator Mikulski for this invitation.

Population studies of cervical cancer occurrences during the past 50 years have documented that cervical cancer is a sexually transmitted disease. Cervical cancer is an infectious disease of coital origin in which an agent or agents are transmitted to susceptible women during sexual intercourse.

Cervical cancer does not arise de novo, anew and of its own accord, without previous intercourse with a high-risk male. Until we change traditional medical thinking about the cause of cervical cancer, failures in cervical cancer screening will continue. Control of cervical cancer will accelerate when the medical community acknowledges the sexual transmission of this disease and the compulsory public health education that must follow.

Although the advent of the Pap test has decreased the number of cervical cancer deaths, cervical precancers, or dysplasias—abnormal conditions preceding cervical cancer—have increased at an alarming rate in women less than 35 years of age.

Changes in sexual mores, increased spacial mobility of susceptible populations, and the upsurge in venereally-transmitted human papilloma virus, HPV, have caused this upturn of cervical precancer or dysplasia.

HPV is one of the fastest-growing silent epidemics in the United States, with millions of new cases occurring each year. HPV is strongly linked to cervical cancer and has also been implicated in accelerating the growth of cervical precancer in young women.

These changes in the biologic behavior of cervical precancer and cancer have undoubtedly magnified the present failures and pitfalls of Pap smear testing in the United States.

Presently at issue is why women who have had Pap tests continue to develop and die of invasive cervical cancer. The number of women who die of this form of cancer each year in the United States and Canada is roughly equivalent to the number of persons who would die if one Boeing 767 plane, carrying 200 passengers, were to crash every week. The public would be outraged if there would be no professional investigation into the cause of the crashes.

Pap smear testing is a paradigm or model of upstream medicine, an opportunity for doctors to educate and to intervene and to alter the course of a disease before its consummation and suffering take their emotional and financial toll on human life downstream.

It is estimated that one out of every three women with cervical cancer or precancer remains undetected following a single Pap smear evaluation.

In 1979, a nationwide study revealed that only 16 percent of clinicians routinely sampled the endocervical canal, the inner portion of the cervix. This finding is alarming, as the medical literature is replete with information regarding the importance of routinely sampling the endocervical canal and combining this sample with a scraping sample from the outer portio of the cervix so as to provide the best possible specimen to the laboratory for cell analysis.

The American College of Obstetricians and Gynecologists stated in 1980, "It has been suggested that more refined techniques may decrease the false negative incidence to as low as 5 percent, but after more than 30 years of physician education, this effort has been spectacularly unsuccessful."

Equally as important is the interpretation of the Pap smear in the laboratory where up to 50 percent of inaccuracies can occur. Cutting the time for evaluation per Pap smear, eliminating costly quality control procedures, and providing little or no continuing cytology education, are the most likely steps a so-called "Pap mill" will take to remain profitable and competitive.

Physicians fail to discriminate between good and bad Pap smear laboratories. The doctor perceives the Pap smear test like a blood smear test, equally performed in all laboratories. Unless a doctor understands the vagaries of Pap smear testing, it is likely that the decision for using one laboratory over another is limited to cost and convenience.

Unknowingly, a woman's Pap smear may be sent thousands of miles remote from where it is taken without knowledge concerning the quality of the Pap smear examination. Local pathology labs must therefore compete on price, since quality issues in Pap smear testing remain unrecognized by many physicians.

Large chain labs, in which the quality of Pap smear testing is a cut above the Pap mills, use the Pap smear as a "lost leader"—discounting the Pap smear price in favor of more profitable, less labor-intensive and automated blood tests. This practice tends to place less emphasis on the critical diagnostic work of cytology as compared to the more profitable automated areas in the laboratory. In reality, the cytology department is one area in the lab where you can kill a woman and not know it at the time.

Inasmuch as we have witnessed a proliferation of knowledge about the infectious nature of cervical cancer with its strong link to HPV, local labs must assume a more important position in controlling this epidemic. Local labs can package crucial data so physicians can devise innovative approaches to patient care, influence community medical practice, and promote public health policy.

Pathologists, cytotechnologists, and physicians must work together in behalf of women in promoting more effective and accurate Pap smear testing and community health education. This cannot be accomplished by a profit-motivated industry.

Also, greater emphasis needs to be placed on contact tracing and screening of male partners of women with cervical cancer and precancer, as cervical cancer is not just a woman's problem; it is our problem.

Pap smear testing must become more personalized and less industrialized.

Control of cervical cancer is a community health problem and should be evaluated by medical personnel trained in the social sciences in order to explore the cultural, socio-economic and behavioral factors contributing to this current epidemic of cervical precancer.

Control of cervical precancer is particularly important because of its grave consequences for women's health. In England, where mortality from cervical cancer in women less than 35 years has doubled in the past decade, a coalition has been formed called WACC, Women Against Cervical Cancer.

Women in America must be informed and concerned. Women must ask questions and take action. Women cannot relinquish their bodies and risk future generations to a Pap smear industry that should have been maintained as a medical science as it was in the beginning.

Thank you.

Senator ADAMS. Thank you very much, Dr. Hasselbrack, for your excellent testimony. We certainly agree with it.

[The prepared statement or Dr. Hasselbrack with an attachment follows:]

Testimony of Dr. Robert Hasselbrack

Director, 5th Avenue Medical Center

Accu-Pap Diagnostics, Inc.

Seattle, Washington

"Cancer Detection in Women"

Senate Committee on Labor and Human Resources

January 28, 1988

Verbal Testimony for the hearing entitled,
"CANCER DETECTION IN WOMEN", by the
Senate Committee on Labor and Human Resources, January 28, 1988.

Population studies of cervical cancer occurrences during the past 50 years have documented that cervical cancer is a sexually transmitted disease. Cervical cancer is an infectious disease of coital origin in which an agent or agents are transmitted to women during sexual intercourse. Simply stated, virgins DO NOT get cervical cancer; 13,000 French Canadian nuns were surveyed annually over 20 years and NO cases of cervical cancer were found. Women with cervical cancer are 5 times more likely to have had sex with men with 20 or more lifetime sexual partners. Cervical cancer does not arise de novo -- anew and of its own accord -- without previous intercourse with a HIGH RISK male.

Until we relinquish traditional medical thinking about the cause of cervical cancer, failures in cervical cancer screening will continue. Control of cervical cancer will accelerate when the medical community acknowledges the sexual transmission of this disease and the compulsory public health education that must follow.

Although the advent of the Pap test has decreased the number of deaths due to cervical cancer, cervical precancers (or dysplasias) -- abnormal conditions preceding cervical cancer -- have increased at an alarming rate, particularly in young women less than 35 years of age. Evidence is accumulating that changes in sexual mores, increased spacial mobility of susceptible populations, and the upsurge in venereally-transmitted human papilloma virus have caused this upturn of cervical precancer (or dysplasia).

Human papilloma virus (HPV) is one of the fastest growing silent epidemics in the United States with millions of new cases each year. HPV is strongly linked to cervical cancer and has also been implicated in accelerating the growth of cervical precancer to cancer in young women. These apparent changes in the biology of cervical cancer have undoubtedly magnified and potentiated the present failures and pitfalls of Pap smear testing in the United States.

Present failures in traditional cervical cancer screening programs can be broadly categorized into six major areas: (1) failure to enlist high risk women into a screening program, (2) failure to identify high risk women in the clinician's office, (3) false negative Pap smears (up to 55 percent) -- attributed to physician sampling error and smear preparation, and errors in laboratory interpretation, (4) misunderstandings between laboratory and physician regarding the significance of cytological findings, (5) lack of adequate patient tracking and follow-up, and (6) patient non-compliance with medical recommendations. It is estimated that approximately 10 percent of women in the United States have never obtained a Pap test.

Presently, at issue is why women, particularly those who have had a Pap test, continue to die of invasive cervical cancer. The number of women who die of this form of cancer each year in the United States and Canada is roughly equivalent to the number of persons who would die if one Boeing model 767 airplane (carrying 200 passengers), were to crash every week. The public would be outraged if there would be NO professional investigation into the cause of the crashes.

Pap smear testing is a paradigm or model of "upstream" medicine -- an opportunity for clinicians to educate and to intervene and alter the course of a disease process before its consummation and suffering take there emotional and financial toll on human life ("downstream" medicine).

It is estimated that one out of every 3 women with cervical cancer or precancer remains undetected following a single Pap smear evaluation. In 1979, a nationwide study revealed that only sixteen percent of clinicians routinely sampled the endocervical canal (the inner portion of the cervix). This finding is alarming as the medical literature is replete with information regarding the importance of routinely sampling the endocervical canal and combining this sample with a scraping sample from the outer portion of the cervix so as to provide the best possible specimen to the laboratory for cell analysis. The American College of Obstetricians and Gynecologists stated in 1980, "It has been suggested that more refined techniques may decrease the false negative incidence to as low as 5 percent, but after more than 30 years of physician education, this effort has been spectacularly unsuccessful." Equally as important is the interpretation of the Pap smear in the laboratory where up to 50 percent of inaccuracies can occur. Cutting the time for evaluation per Pap smear, eliminating costly quality control procedures, and providing little or no continuing cytology education are the most likely steps a so-called "Pap mill" laboratory will take to remain profitable and competitive.

Clinicians fail to discriminate between good and bad Pap smear laboratories. The clinician perceives the Pap smear like a blood smear, equally performed in all laboratories. However, unlike most laboratory tests, the Pap smear is NOT automated and is very labor intensive and requires the critical examination of tens of thousands of cells on a well-stained slide by a trained and certified cytotechnologist. Unless a clinician understands the vagaries of Pap smear testing, it is likely that the decision for using one laboratory over another is limited to price and convenience. Unknowingly, a woman's Pap smear may be sent thousands of miles remote from where it is taken without knowledge concerning the quality of the cytological examination performed. Local pathology laboratories must compete on price, since quality issues in Pap smear testing remain unrecognized by many clinicians. Large chain laboratories in which the quality of Pap smear testing is a cut above the "Pap mills", use the Pap smear as a "lost leader" -- discounting the Pap smear price in favor of more profitable, less labor intensive, and automated blood tests. This practice tends to place less emphasis on the important diagnostic work of the cytology department as compared to the more profitable automated areas in the laboratory. The reality is the cytology department is one of the few areas in the lab where you can kill a woman and not know it at the time.

Inasmuch as we have witnessed a proliferation of knowledge about the infectious nature of cervical cancer with its strong link to human papilloma virus, local cytopathology laboratories must assume a more important position in controlling this epidemic. Local laboratories can package crucial data so physicians can devise innovative approaches to patient care, influence community practice, and promote public health policy. Pathologists, cytotechnologists, and clinicians must work together in behalf of women in promoting more effective and accurate Pap smear testing and community health education. This cannot be accomplished by a profit motivated industry.

For Pap smear testing to be successful, the patient, clinician, pathologist, and cytotechnologist must communicate and work together effectively, know their responsibility, and follow the guidelines for optimal cervical cancer screening and ultimately disease prevention. In addition, greater emphasis needs to be placed on "contact tracing" and screening of male consorts of women with cervical cancer and precancer, as cervical cancer is not just a woman's problem, it is OUR problem. Pap smear testing must become more personalized and less industrialized.

Control of cervical cancer now becomes a community health problem to be evaluated by medical personnel trained in the social sciences, in order to explore the cultural, socioeconomic, and behavioral factors contributing to this current epidemic of cervical cancer. Control of cervical cancer is particularly important because of its grave consequences for women's health. In England, where mortality from cervical cancer in women less than 35 years of age has doubled in the past decade, a coalition has been formed called WAAC - Women Against Cervical Cancer. Women in America must be informed and concerned. Ask questions and take action. You cannot relinquish your bodies and future generations to a Pap smear industry that should have been maintained as a medical science.

OPINION ARTICLE APPEARING IN CAP TODAY*, FEBRUARY, 1988

The pathologist's most important skill is the ability to make an accurate and timely assessment of a patient's pathophysiologic condition. Collating and communicating the findings and educating others are inseparable components of this skill. This vital laboratory information is interpreted meaningfully for the clinician, who ultimately chooses the best possible course of action for the patient. Regrettably, this scenario is not always fulfilled, as the public has been made painfully aware in recent media reports, including the November 2, 1987 Wall Street Journal account, "The Pap Test Misses Much Cervical Cancer Through Labs' Errors."

One person's labor of love and life dedicated to science has culminated in an "industry," as Pap testing has been called. Were George Papanicolaou -- the CEO of the Pap smear "industry" -- alive today, he would probably shed a tear and say quietly: "How can we recall a woman's life?"

At issue is why women, particularly those who have had a Pap test, continue to die of invasive cervical cancer. The number of women who die of this form of cancer each year in the United States and Canada is roughly equivalent to the number of persons who would die if one Boeing model 767 airplane (carrying 200 passengers), were to crash every week. Certainly there would be professional investigation into the cause of the crashes.

Many of the women who die of cervical cancer fail to have a Pap test done at all or with the recommended frequency. Still, the shortcomings of cervical cancer screening -- whether it be careless work or an inability to convince all women of its importance -- can no longer be ignored.

As pathologists we now must acknowledge and address the failures of cervical cancer screening in the United States and return the science to Pap smear testing. This surely will not be done by a profit-motivated "industry". Cervical cancer screening needs to become less industrialized and more personalized. A percentage, a number, a statistic loses its meaning when it bears no name or face. Pap smear testing is a paradigm of "upstream" medicine -- an opportunity for pathologists to intervene and alter the course of a disease process before its consummation and suffering take their emotional and financial toll on human life ("downstream" medicine). We need to shift our emphasis on illness to a concern for health.

In the past decade, we have witnessed a proliferation of knowledge about the infectious nature of cervical cancer and lower genital tract neoplasia with its link to human papilloma virus (HPV). HPV appears to be one of the fastest growing sexually-transmitted disease epidemics in North America. Pathologists can assume a pivotal role in controlling this burgeoning worldwide public health problem, and recapture our fundamental role in medical society as modern day "cellular epidemiologists". We have as our mentor and model the most venerated scholar in pathology, the German pathologist, Rudolph Virchow (1821-1902).

*College of American Pathologists (monthly newsletter)

Most contemporary pathologists think of Virchow as physician-scientist and founder and first editor of Archiv, a premier journal of medical studies still with us today, and author of Cellular Pathology, which transformed medical thinking in the 19th century. Virchow's professional life also included the investigation of epidemics, laboratory discoveries, the use of statistics and financial considerations (i.e., cost-benefit analysis for influencing sanitary policy in Berlin), and essays on "Responsibility", "Diminished Responsibilities", and negligence in "Technical Medical Errors." Using Virchow as an example, we must become the local repository of invaluable clinical information. We must package these crucial data so physicians can devise innovative approaches to patient care, influence community practice, and promote public health policy. We must act on behalf of women patients and work in concert with clinical colleagues in promoting more effective and accurate Pap smear testing.

For Pap smear testing to be successful, the patient, clinician, pathologist, and cytotechnologist must communicate and work together effectively, know their responsibilities, and follow the guidelines for optimal cervical cancer screening and ultimately disease prevention. In the face of limited financial resources, pathologists must cooperate with health care agencies, medical speciality groups, local governmental regulatory agencies, employers, and third party payors. We need to make the most of fewer health care dollars and offer the greatest value possible to the woman who relies on the medical system for accurate screening and diagnosis.

That which pathologists cannot see is often their greatest moment in medicine: a life saved from the ravages of disease because they cared enough to do their best. We cannot relinquish these precious moments to an "industry" obsessed with profit.

Dr. Hasselbrack is founder of ACCU-PAP Systems, Director of ACCU-PAP Diagnostic Services and Pathologist and Laboratory Director at Fifth Avenue Medical Center, Seattle.

FOR WOMEN ONLY: A HEALTH CONSUMER'S GUIDE FOR AVOIDING THE PITFALLS IN PAP SMEAR TESTING

QUESTIONS TO ASK YOURSELF BEFORE YOUR PAP SMEAR TEST APPOINTMENT

1. What should I expect for my Pap smear exam, and how can I ensure my results will be reliable?

* The Pap test is an essentially painless procedure developed for routine screening of women for cervical cancer and precancerous conditions. Optimally, the Pap test is intended to detect cervical abnormalities early so that they can be treated and cured, thus eliminating the possibility of progression to cancer. It may also detect several common cervical and vaginal infections, including human papilloma virus (HPV) and other sexually transmitted diseases. The Pap test failure rate for detecting cervical cancer and precancerous conditions varies greatly -- between 5 and 55 percent, depending on: (1) whether you have been given and followed appropriate instructions before the Pap test examination (see question #2), (2) how your clinician obtains and prepares your Pap smear, (3) how your Pap smear is examined in the pathology laboratory your clinician uses, (4) the level of communication - CONSULTATION - between your clinician and the laboratory's pathologist/cytotechnologist, (5) the level of communication between you and your clinician, and (6) the size and location of the precancerous or cancerous growth and its biologic behavior (NOT directly related to clinician or laboratory performance). Even when performed by the BEST clinicians and interpreted in the BEST pathology labs the Pap test result is NOT 100 percent accurate. Nonetheless, 95 percent accuracy is achievable on a single Pap smear examination, if you, your clinician, the pathologist, the cytotechnologist communicate and work effectively together and follow the guidelines for optimal cervical cancer screening.

2. Have I received and followed the appropriate instructions to prepare for my Pap smear exam?

* Not every clinician's office or clinic will remind you each time of the correct way to prepare for a Pap smear. If you don't follow the right procedure, you may be reducing the accuracy of your Pap smear interpretation and result, regardless of the professionalism and expertise of your clinician and pathology lab. If you have a false negative test (you have disease, but the test results say you don't), you and your clinician end up with false security and you may suffer the consequences of delayed treatment. On the other hand, if you have a false positive test (you don't have

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disease, but the test results say you do), you may end up with needless additional tests and/or treatment. You can help eliminate missed opportunities for early cervical cancer detection or avoid a false positive test, if you ask your clinician's office for specific instructions about preparation for a Pap smear prior to making your Pap test appointment. Your clinician may suggest: to refrain from intercourse, to avoid use of douches, contraceptive jellies or foams, and intra-vaginal medication for at least 48-72 hours prior to taking the Pap smear; to have the Pap smear taken between the 12th and 16th day of the 28 day menstrual cycle.

3. Have I written down important questions to ask my clinician, and do I fully understand the importance of my medical examination?

* Your clinician should eliminate any anxiety or apprehension you may have about the examination procedure. S/he should be willing to spend the necessary time to answer all of your medical questions in clear and simple language. The appointment time spent with your clinician includes: (a) appropriate medical history-taking, including your sexual behavior, (b) a physical examination and lab tests based on your age, current physical signs and/or symptoms, (c) consultation and health education/information -- education about breast self-examination, sexual behavior that increases risk for sexually transmitted diseases, birth control, the risks associated with smoking, stress reduction, diet, etc. After you leave the office, you should have a clear understanding about all of your medical concerns -- written and verbal, and what you can do to protect your health, and what your responsibilities are.

4. Have I been completely honest and open about my medical and pregnancy history, my nonprescription and prescription drug history, and my sexual behavior?

* No matter how professional and responsible your clinician is, s/he cannot maximize the accuracy of your Pap test or determine whether additional tests are necessary, unless you are completely honest. Your best interests are served by being open and honest about your health, sexual behavior, previous sexually transmitted diseases, and sexual relationships with "high risk", promiscuous males, at least in conference with your clinician. Your medical history and clinical information is held in confidence, and laws protect your privacy. The momentary embarrassment you may experience pales next to serious complications from undetected sexually transmitted diseases, and/or death from cervical cancer.

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5. Am I willing to make the necessary changes in sexual behavior and life style, if my clinician indicates that I am engaged in activities injurious to my health or the health of my sexual partner?

* Remember, your body is your responsibility. You and your clinician must establish mutual understanding and realistic expectations for a healthful life. If after the medical interview and examination it is apparent you are engaged in activities injurious to your health, your clinician can advise and assist you in making appropriate behavioral changes; but ultimately, the health of your body is in your control, and you must make the decision and take the necessary steps for a more healthful and productive life.

YOU ARE IN A HIGHER RISK GROUP FOR HPV-ASSOCIATED CERVICAL PRECANCER OF CANCER IF:

- You have had a history of genital warts (papilloma virus) or genital herpes
- A previous Pap smear showed abnormal or suspicious cells
- You began intercourse at an early age (before 18)
- You have had more than three sexual partners in your lifetime
- You do not use barrier methods of contraception and/or you take "the pill"
- Your sexual partner has had intercourse with a woman who developed genital HPV, cervical cancer, or its earlier stage (precancer)
- Your mother took DES (diethylstilbestrol), prescribed for threatening miscarriage during her pregnancy with you
- You smoke
- Your immune system is deficient (discuss this with your clinician)

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QUESTIONS TO ASK YOUR CLINICIAN BEFORE YOUR PAP SMEAR EXAMINATION

1. What is the significance of human papilloma virus (HPV) to cervical cancer and who is at risk to develop it?

* If your clinician does not inform you about the venereal transmission of cervical cancer, the connection of sexually transmissible HPV and cervical cancer, and if s/he does not discuss with you the sexual behaviors and other factors that put women at risk for cervical cancer, AIDS, and other sexually transmitted diseases, find another clinician who is more informed and who will counsel you about matters important to your health. Clinicians must make patients aware that HPV is another potentially lethal sexually transmitted disease and to advocate "safe" sexual practice. In the long term, HPV may have a greater potential for serious disease in more individuals than AIDS.

2. What cervical sampling device(s) do you use and how will my Pap smear be obtained?

* Your clinician must be willing to explain the Pap smear testing procedure with you. The explanation should be presented so that you clearly understand what the cervix looks like and the specific area from which the cervical sample is obtained. Optimally, the endocervical canal -- the area beyond the opening of the cervix -- must be sampled with a plastic tube (for suction of mucus and cells), or with a small "brush", or with a saline-moistened cotton swab. This sample must be combined with a "scraping" sample from the outer surface of the cervix, preferably using a plastic spatula. If your clinician says, s/he only uses a wooden tongue blade and s/he's been doing it this way for years and never had a problem, find another clinician, or get a second opinion. Your clinician should be familiar with state-of-the-art cervical sampling techniques and the importance of obtaining a representative sample from the critical area from which most cervical cancers arise.

3. Once the sample is taken, how is my Pap smear prepared for accurate examination in the pathology laboratory?

* A properly prepared Pap smear in the clinic is just as important as collecting the appropriate sample from the right area of the cervix. Unlike most specimens sent to the laboratory, optimal preparation of the Pap smear is entirely dependent upon the expertise of the clinician and his/her assistant. Pap smear preparation requires the skill of a

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healthcare professional -- a clinician, a nurse, a trained medical aide, for example. If you think your clinician uses uninformed assistants or unskilled personnel to prepare your smear, you may call the Pathology laboratory your clinician uses. (Good pathology laboratories are aware of their clinician's cervical sampling and slide preparation techniques and will report back to them important information about the quality of their Pap smears).

4. How do you label my Pap smear/slide for identification at the pathology lab?

* Your name must be written on the frosted end of the slide. Mislabeling of slides and mixing up slides in the office or in the pathology lab is all too easy. Ultimately, your name on the slide must be matched with your name on the accompanying Pap smear requisition form sent to the pathology lab.

5. What information will be sent to the pathology lab along with my Pap smear?

* Your pertinent medical history, date of last menstrual period, and sexual history (e.g., type of contraceptive used, number of life-time sexual partners, age at first intercourse, and other critical risk factor information), plus important clinical observations and impressions (e.g., visible abnormalities on the cervix) must accompany your Pap smear, in order to identify women at high risk for cervical cancer. (Remember, medical information is held in confidence, and laws protect your privacy.) If your clinician only sends billing information and cursory medical information (such as whether or not you are pregnant), look elsewhere for a clinician to perform your Pap smear.

6. What pathology lab will you be sending my Pap smear to, and where is it located? What do you know about the laboratory, the pathologists and cytotechnologists, and how often do you discuss problem cases with them?

* The pathology lab should be local (in the same town as the clinician, or in a neighboring community). If not, there should be a good reason for using a distant lab. Your clinician should be able to tell you something about the pathologist(s), the pathology lab's professional reputation, licensing, accreditation, the qualifications of lab personnel performing the lab tests, and the screening workloads for the cytotechnologists. The Pap smear interpretation should be conducted in a pathology lab, 'NOT in the cytologist's home or

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in the clinician's office. Unlike the majority of laboratory tests, the Pap smear is a very labor-intensive test and must be performed by a qualified/certified cytotechnologist with a pathologist's supervision and consultation close by. The Pap smear examination is an exacting job and requires subjective evaluation of tens of thousands of cells on a well-stained adequate smear to determine if any abnormality exists. A pathologist will examine your Pap smear if the cytotechnologist discovers abnormal cells and/or the clinical history warrants additional review. The Pap smear report should be considered a CONSULTATION from the cytotechnologist and pathologist to your clinician. If an abnormality exists, it should be clearly communicated to your clinician and appropriate action must be taken to ensure your continued well being.

If your clinician tries to sell you on the idea that s/he is doing you a favor by finding the least expensive lab services (sometimes thousands of miles away or sometimes right in the clinic, using a "contract" in-house and unsupervised cytotechnologist), find another clinician. You want the best, not the cheapest service.

7. Will I receive a report of my Pap smear results, regardless of a negative or positive outcome?

* You are paying for the lab work, and have every right to receive a clear explanation of the results. Don't settle for "no news is good news." You may not have heard from your clinician's office because of a mix-up, a lost Pap smear, or a misplaced report or some other miscommunication. If you haven't heard by the time you receive your bill, call the office for your Pap smear result. If your results are abnormal, you should have a clear understanding of what the abnormal condition is and what you should do next. Ask questions and if you are still uncertain or not satisfied with your clinician's response, obtain a second opinion. You should also ask to have your previous "normal" Pap smear reviewed.

8. Will I receive a bill for my Pap smear from the pathology laboratory?

* If your clinician says "no", this may be a red flag. Ask your clinician if the cytotechnologists employed by the lab are: registered/certified; working in the lab or at home; mostly full-time or part-time; salaried or paid by the number of slides screened (piecework pay schedule) or by some other incentive payment, e.g., permitted to leave work early - as soon as they have fulfilled their daily quota. Chances are that more often clinic-billed Pap smears vs. patient-billed

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Pap smears are sent to a laboratory, sometimes distant or out-of-state, where quality control is minimal and pay incentives exist that encourage rush Pap smear screening. Cutting the time for examination per Pap smear, eliminating costly quality control procedures, and providing little or no continuing cytology education are the most likely steps a laboratory will take to remain profitable and competitive. A charge to the clinic of less than $4.50 per/case (year 1987) could mean a high volume, marginal laboratory without good quality control. You should also be aware that some large chain laboratories use the Pap smear as a "loss leader" -- discounting the Pap smear price in favor of more profitable, less labor-intensive and automated blood tests. This practice tends to place less emphasis on the important diagnostic work of the cytology department as compared to other more profitable areas in the laboratory.

9. Will I receive a reminder notice of when I should return for my next Pap smear?

* You and your clinician should candidly discuss your level of risk for developing cervical cancer or other sexually transmitted diseases, (and what important signs and/or symptoms that should prompt you for a non-routine medical examination). Presently, there is debate among professional organizations about the appropriate Pap smear screening interval for women in America. If you have been honest about your sexual history, and you have had a satisfactory pelvic exam, and you and your clinician can be confident about your Pap smear report, then you and your clinician can decide what Pap smear screening interval is best and safest for you. Make a note of the return date and ask your clinician to send you a reminder notice, (assuming your current Pap test will be normal).

Finally, in order for you to receive the best possible healthcare and advice, you must be an informed and responsible patient. If your clinician resents your questions or expects you to implicitly trust him/her, find a clinician that appreciates your interest in your own healthcare. They do exist (there are more of them each year) and they are better clinicians than those who insist on supreme authority over your healthcare. Whereas it is true that clinicians are very well educated and extensively trained, they are not all-knowing nor all-wise. (As for example, many clinicians are unaware of the major problems and pitfalls associated with cervical cancer screening and lack information about choosing a good Pap smear laboratory). The more you, as a patient, can express your concerns and participate in your healthcare, the better job your clinician and his/her Pap smear laboratory

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will be able to do. Good clinicians and pathologists know that. Remember, your clinician works for you; however, when you buy into your clinician's decision-making process, you may get more or less than you bargained for.

BE ASSERTIVE -- BE CONCERNED -- BE EDUCATED -- BE PREPARED

Janet Anderson
Robert Hasselbrack

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FOR MEN ONLY: A PARTNER'S GUIDE FOR PREVENTION OF CERVICAL CANCER

WHAT YOU SHOULD KNOW ABOUT CERVICAL CANCER:

- Cervical cancer is an infectious disease spread through sexual intercourse from male to female.
- Cervical cancer DOES NOT arise de novo (anew and of its own accord) without previous sexual intercourse with a HIGH-RISK male. *
- Cervical cancer is a preventable disease (and nearly always curable with early detection).
- Virgins DO NOT get cervical cancer; (13,000 French Canadian nuns were surveyed annually over 20 years and NO cases of cervical cancer were found).
- Medical experts believe that cervical cancer is a venereal disease strongly linked to a highly contagious sexually transmitted group of viruses known as human papilloma virus (HPV).
- Other harmful factors or agents such as cigarette smoking and herpes virus infection may help the development of cervical cancer.
- Ninety per cent of invasive cervical cancers show evidence of prior HPV infection.
- Among women with cervical precancer and HPV, 60 to 80 per cent of their male partners have a hidden source of HPV in the genital region.
- It is estimated that 6 per cent of males and 10 per cent of females will have genital HPV at some time during their life; some medical experts estimate that lifetime exposure to HPV may be as high as 25 per cent.
- HPV is a sexist disease because women get cervical precancer or cancer, and may lose their reproductive function or die. In contrast, few men get cancer of the penis and lose their penis or die.
- You may have genital HPV and not be aware, but still capable of infecting your sexual partner.

* males who are more likely to carry and spread cancer-causing HPV and other sexually transmitted diseases to susceptible women

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- HPV may remain dormant in the genital region for months and possibly years without any signs or symptoms. When the body's immune system breaks down, clinical signs of HPV - genital warts - may appear.

- A vinegar wash of the genital region, proper illumination, and careful examination with a magnifying lens are necessary for finding HPV. Newer laboratory tests for detecting HPV are now available to clinicians.

- If you have HPV, a condom may not offer complete protection to your partner. Infected surfaces not protected by the condom may still transmit HPV.

- You are a HIGH-RISK male if:

  (1) You have had multiple sexual partners; (women with cervical cancer are five times more likely to have had sex with men with 20 or more life-time sexual partners)

  (2) You had sex with a woman who developed cervical cancer, precancer, or HPV

  (3) You have a history of previous sexually transmitted diseases, especially genital warts (HPV)

  (4) You have a history of genital cancer, especially penile cancer

  (5) You have had sex with prostitutes; (prostitutes are a natural reservoir for HPV and other sexually transmitted diseases)

WHAT YOU CAN DO TO PROTECT YOUR PARTNER FROM CERVICAL CANCER:

- Maintain a stable, long-term, unquestionably trusting relationship with one partner.

- Avoid casual sex, particularly with promiscuous women and prostitutes. You may infect yourself as well as your next partner with a potentially lethal disease.

- Know your partner; ask each new partner whether she has had HPV (genital warts), cervical precancer or cancer, or any other sexually transmitted disease.

- Practice disease-preventative measures and protective sex. Use a condom and urge your partner to use a diaphragm plus vaginal spermicides containing Nonoxynol-9, regardless of need for birth control.

- Avoid anal contact and other injurious sexual practices.

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- Refrain from sexual activities in the presence of any unusual genital signs or symptoms, such as warts, ulcers, sores, or urethral discharge.
- Ask questions of your sexual partner; and become informed of the appearance of suspicious genital lesions.
- If a sexually transmitted disease has been diagnosed, avoid sexual activity until treatment has been completed and a follow-up medical examination shows no infection. You must also immediately inform your most recent sexual partner(s) and encourage them to seek medical attention.
- If you are sexually active, obtain regular physical examinations, and encourage your partner to have regular physical examinations with Pap smear evaluations. In the female, the Pap test remains the mainstay for detecting HPV. No such screening method currently exists for the male partner; however, newer HPV typing tests may become an important diagnostic tool for men, as well as for women.
- Find a clinician who is knowledgeable and current about genital human papilloma virus and other sexually transmitted diseases. S/he should be informed about the latest procedures for accurate diagnosis, treatment, and preventative measures.
- If a medical examination reveals genital warts (HPV), they should be removed to prevent further spread of a highly infectious sexually transmitted disease.
- Be honest and candid with your clinician about your sexual activities and ask questions.

CONCLUSION:

HPV is one of the fastest growing, silent epidemics in the U.S., with millions of new cases occurring each year. Men harboring HPV become part of an expanding infectious disease pool for sustaining and transmitting this cancer-causing virus to susceptible women. Men must assume greater responsibility in a community-based effort against the epidemic of human papilloma virus. HPV is not only a serious, complicated, and potentially lethal disease, it is also a serious social disease that threatens the future of young women becoming healthy adults capable of reproduction. Since a vaccine is not in the foreseeable future, it is necessary to emphasize prevention. The basic message of prevention is simple. Men must stop sexual transmission of HPV by engaging in mutually monogamous relationships, or, if not, by practicing protective sex, and having regular medical examinations, and when necessary, treatment by informed and concerned clinicians. In the long term, HPV may have a greater potential for serious disease in more individuals than AIDS.

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CERVICAL CANCER IS AN INFECTIOUS DISEASE THAT IS SPREAD THROUGH SEXUAL INTERCOURSE!

Genital human papilloma virus (HPV) is significantly linked to the development of cervical dysplasia--abnormal growths that may become cancerous--and is closely associated with 90% of invasive cervical cancers. Squamous cell cancer--the most common type of cervical cancer--has not been reported among virgins, and is uncommon in long-term unquestionably monogamous relationships.

Since medical scientists know that genital HPV is a sexually transmitted disease, and clinicians can treat it effectively before the virus starts or promotes the cancerous process, we now know how to control and treat this potentially lethal disease.

That's why it is important for you to know about genital human papilloma virus (HPV) and other cervical cancer risk factors. In the long term HPV may have a greater potential for serious disease in more individuals than AIDS.

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WHAT IS GENITAL HPV?

Genital human papilloma virus (HPV)--venereal wart(s)--is one of the fastest growing, silent epidemics in the U.S., with millions of new cases occurring each year. About 10% of American women have HPV infections at some point in their lives. Viruses typically invade normal cells and tissue and take control; when the HPV virus is apparent in the body, it commonly causes wart-like growths, or for unknown reasons, it may remain dormant and without any signs for an indeterminate period of time. Wart outbreaks may occur when the body's disease defense mechanism is decreased -- during pregnancy or chemotherapy.

Over 50 types or strains of HPV have been identified, each having preference for a certain site in the body -- skin, mouth, throat, or genital areas (penis, scrotum, cervix, vagina, vaginal opening, and areas surrounding the anus and vagina). At least ten of the known types of HPV affect the genital areas with a disease commonly known as condyloma or venereal warts. Of these ten types of genital HPV, eight are associated with progressive precancerous growths which rapidly can become cancerous without treatment.

It is the opinion of many medical scientists and public health officials that cervical neoplasia (precancer and cancer) will continue to increase among young women, unless genital HPV and HPV-associated precancerous cervical growths are controlled. If genital HPV is not controlled, there may be an increased loss of reproductive function in younger women and more deaths from invasive cervical cancer.

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HOW IS GENITAL HPV TRANSMITTED?

Viruses can survive in nature only if they are able to pass from one individual "carrier" to another. Genital HPV is passed from one infected person to another through tiny areas of injury to the penis, vulva, vagina, or cervix during sexual intercourse. Normally, genital HPV will not result in any signs or symptoms for a period of one to twenty months or longer after transmission.

A seemingly healthy partner can pass the virus along without knowing he or she has it.

Genital HPV is pathologically sexist; that is, they discriminate against women. Women become infected more easily and tend to have more severe complications than men. The virus is found most often among sexually active young adults who have had multiple sexual partners.

There is little doubt that anyone who has multiple sexual partners is at risk for becoming infected--the more partners a woman or man has had, the greater her/his risk of carrying genital HPV.

There is NO danger of genital HPV infection by casual nonsexual social contact or from spread of common skin warts occurring in nongenital areas. Genital HPV is transmitted through sexual contacts with infected persons.

Rarely, the unborn child of a genital HPV-infected pregnant woman can be adversely affected while inside the uterus or during passage through the infected birth canal. Although relatively uncommon, children born to infected mothers may develop laryngeal (throat) warts and anal warts. Laryngeal warts in infants can be extremely dangerous.

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WHAT ARE THE SIGNS AND SYMPTOMS OF GENITAL HPV?

Most women with genital HPV infections involving the cervix and vagina are not aware of the disease, because there may not always be discernible signs or symptoms. Genital HPV can cause warts appearing on the external surfaces - vaginal opening and areas surrounding the vagina and anus - as fleshy, moist, pinkish-red to grayish-white, soft skin growths. When warts occur in the vagina or on the cervix, they are usually without symptoms, flat and often invisible without the use of topical 5 percent acetic acid (vinegar solution) and special examining equipment.

A Pap smear that includes a sampling of cells from the cervical area usually reveals the presence of atypical cells (koilocytes or hollow cells, dyskeratotic and hyperkeratotic or abnormally orange cells) which are only some of the significant findings associated with genital HPV infection. If your Pap smear contains these abnormalities, you should have further diagnostic tests and treatment.

New screening tests are capable of detecting specific strains (types) of genital HPV in both men and women. These HPV typing tests are now available.

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IF MY ANNUAL PAP SMEAR IS NEGATIVE, CAN I BE SURE THAT I DON'T HAVE GENITAL HPV?

Presently, the Pap smear is the most effective and practical method for detecting cervical disease, even when there are no symptoms. However, the failure rate for detecting genital HPV and HPV-related cervical dysplasia varies greatly - between 5 and 55%, depending on: (1) whether you have received and followed appropriate instructions before coming in for the Pap test, (2) how your clinician obtains and prepares the specimen, (3) how the Pap smear is analyzed in the cytopathology laboratory your clinician uses, and (4) the level of communication - consultation - between you and your doctor and pathologist/cytotechnologist.

When all conditions are favorable, a single Pap test can be accurate in 90% - 95% of cases. Combining a detailed sexual history, a thorough pelvic examination, Pap smear testing, colposcopy (see forthcoming section), and genital HPV testing (typing) can elevate diagnostic accuracy close to 100%.

It is important for you to be candid with your clinician about your sexual history and other cervical cancer risk factors. Without this information, your clinician cannot determine how frequently you should receive a Pap smear, and whether additional testing is indicated for genital HPV and/or other sexually transmitted diseases.

WHAT RISK FACTORS ARE ASSOCIATED WITH CERVICAL CANCER?

You are in a higher risk group for HPV-associated cervical precancer or cancer if:

- You have had a history of genital warts (papilloma virus) or genital herpes
- A previous Pap smear showed abnormal or suspicious cells
- You began intercourse at an early age (before 18)
- You have had more than three sexual partners in your lifetime
- You do not use barrier methods of contraception and/or you take "the pill"
- Your sexual partner has had intercourse with a woman who developed genital HPV, cervical cancer, or its earlier stage (precancer)
- Your mother took DES (diethylstilbestrol), prescribed for threatening miscarriage during her pregnancy with you
- You smoke
- Your immune system is deficient (discuss this with your clinician)

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HOW IS GENITAL HPV TREATED?

Treatment for HPV is directed toward the "wart" or area of abnormal tissue. Treatment is usually accomplished by application of chemicals (trichloracetic acid or podophyllin), heat (cautery or carbon dioxide laser), or cold (liquid nitrogen or cryotherapy).

Flat warts that affect the cervix cannot be managed in the same way as skin warts. First, they are difficult to see without magnification. Your clinician will use a vinegar wash and a colposcope - a binocular-like instrument that magnifies 7 to 20 times - to visualize warts. Second, a small tissue sample (biopsy) will be taken from the abnormal area for analysis by a pathologist.

Third, after review of the biopsy report from the pathologist, your clinician will proceed with treatment that is most appropriate for you. Surgical removal of cervical warts (conization) is seldom indicated, as they can be destroyed through heating (carbon dioxide laser) or freezing (cryotherapy) techniques. The newest treatment being studied (now experimental) is Interferon--an antiviral agent that is applied directly to the affected area. When extensive involvement of the vagina is discovered, your clinician may prescribe a vaginal cream containing 5-Fluouracil, which is known to be effective for treatment of venereal warts.

Treatment may not always be successful during the first course. It is uncertain whether treatment failures result from small, undetected and untreated satellite lesions, reinfection by a sexual partner, or the appearance of viruses previously dormant (latent) in normal appearing tissue adjacent to treated warts.

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IF I HAVE GENITAL HPV INFECTION, WHAT SHOULD I TELL MY PARTNER?

You must inform your current partner(s) that you have genital HPV. As many as 85% of women acquiring genital HPV have had recent intercourse with men having similar disease, and often the same genital HPV type. Most men are unaware of any problem and have no symptoms. Even if your partner does not think anything is wrong, he should be examined by a clinician who is knowledgeable about genital HPV. A male's right to privacy is far less important than the danger of spreading this major and potentially lethal virus.

An untreated male remains a potential source of reinfection to you, and a continual source of disease transmission to other susceptible sexual partners. Also, extremely small and/or invisible genital warts may increase in size or number rapidly. Cancerous transformation of untreated penile lesions, although rare, can also occur.

You may want to encourage your partner to try a simple home test. Soak a towel in equal amounts of vinegar and water. Then wrap the penis and scrotum in the towel for three to five minutes. Warts will show as flat or as white bumps, single or multiple, occasionally associated with areas of red, gray, or brown discoloration. Genital warts can also occur on the pubis (above the base of the penis), perineum (between the scrotum and anus), perianal area (around the anus), urethra (inside the penis), and anal canal. If questionable abnormal growths are present, a physician can evaluate them with a vinegar wash, a special magnifying lens, and a tissue sample (biopsy). These steps will determine whether the growths are genital warts or look-a-likes (harmless skin abnormalities not requiring aggressive treatment).

The increased risk of sexual transmission of potentially cancer-producing HPV in the uterine cervix and the external genitalia emphasizes the importance of detection and treatment of all HPV-associated male-genital lesions in the prevention of cervical cancer.

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HOW CAN I PROTECT MYSELF FROM GENITAL HPV?

Abstinence from sexual intercourse is the only absolute protection from genital HPV and other sexually transmitted diseases. Obviously, this is unacceptable for most sexually active adults. A long-term sexual relationship in which both partners are disease-free and have remained faithful to each other also carries no risk. However, a person can carry genital HPV virus for up to twenty months or longer before it results in abnormal findings. Other sexually transmitted diseases, such as gonorrhea, AIDS, herpes, hepatitis B, chlamydia, and intestinal bacteria may also be without symptoms, and infected persons may be impossible for you to identify.

KNOW YOUR PARTNER!

Since you can't readily identify disease-infected people, the best protection from genital HPV is to reduce the number of sexual partners. You should also avoid sexual activities with persons--HIGH RISK MALES--known to have had numerous partners. These men serve as a reservoir of sexually transmissible, potentially cancer-producing genital HPV. The use of latex condoms, diaphragms, plus vaginal spermicides will also help reduce, but does not completely eliminate, the probability of disease transmission (genital warts can still be transmitted by infected surfaces not protected by the condom).

Another way in which you can protect yourself is to visually inspect your partner, and refrain from sexual activities if you observe sores, growths, or discharge. If a sexually transmitted disease has been diagnosed, avoid sexual activity until treatment has been completed. Avoid receptive anal contact, as the anal epithelium is more prone to minitears which can provide entry for disease microorganisms.

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Summary and Conclusions

All sexually active women must have a yearly pelvic examination and Pap smear evaluation by their clinician. The clinician provides visual inspection of the lower genital tract--vaginal opening and surrounding area, vaginal canal, and cervix using special lighting. He or she then collects a sample of cells and fluids from the cervix and endocervical canal and spreads them on a glass slide for evaluation under a microscope by a cytotechnologist. A pelvic examination is performed. (Depending on signs and symptoms, your clinician may want to perform additional laboratory tests, for example HPV typing).

The cytotechnologist and/or pathologist who evaluates the Pap smear provides your clinician with a detailed report of their findings and recommendations. When the Pap test is properly performed, this simple procedure of obtaining cells and fluids from the cervix-endocervical area is effective in diagnosing a wide variety of troublesome conditions in their early stages when outpatient treatment is practical and cure is achievable. Your clinician can then use this laboratory information to determine the most appropriate health care recommendation for you as an individual.

The majority of HPV's - about 90 percent - causing genital warts and condylomas are benign (non-cancerous). Certain HPV types, however, have been strongly associated with lower genital tract malignancies. Studies have shown that, more frequently, non-cancerous genital warts and mild cervical disease (dysplasias) are associated with HPV types 6 or 11. In contrast, types 16, 18, 31, 33, 35, 39, 42 and 45 have been associated with severe dysplasias and invasive cancers. Presently, most physicians recommend that whenever possible genital warts and condylomas should be treated for cure, regardless of type. Men and women known to harbor high risk HPV types--those HPV's capable of promoting cancer--should have more frequent medical examinations. Discuss this with your clinician.

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TO PROTECT YOURSELF FROM CERVICAL CANCER AND TO REMAIN FREE OF OTHER SEXUALLY-TRANSMITTED DISEASES (STD's):

. Know your partner; Ask each new partner whether he has had an STD.

. Avoid casual sex, particularly with promiscuous men having had multiple partners, bisexual and homosexual men, and I.V. drug users.

. Maintain a stable, long-term, unquestionably trusting relationship with one partner.

. Practice disease-preventive measures. Use barrier contraceptive methods (latex condoms, diaphragms, plus vaginal spermicides containing nonoxynol-9), regardless of need for birth control.

. Avoid receptive anal contact and other injurious sexual practices.

. Refrain from sexual activities in the presence of any unusual genital signs or symptoms, such as warts, ulcers, sores, or urethral discharge.

. If an STD has been diagnosed, avoid sexual activity until treatment has been completed and a follow-up medical exam shows no infection.

. Question, and do not hesitate to inspect a potential partner for genital lesions.

. Obtain regular Pap smear evaluations.

. Be honest and candid with your clinician about your sexual activities and ask questions.

. Encourage your partner(s) and friends to have regular checkups, and practice personal prevention.

Prevention through education is the ultimate goal for containing the spread of genital human papilloma virus (HPV), cervical cancer, AIDS, and other sexually-transmitted diseases.

BE ASSERTIVE--BE CONCERNED--BE EDUCATED--BE PREPARED

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FAILURES OF CERVICAL CANCER SCREENING IN THE U.S.

CLINICIAN PERFORMANCE FACTORS

1. Inadequate Pap Smear Test Preparation Instructions to Women

* If patients do not receive clear instructions as to how to prepare for the Pap test (e.g., the best time of the month for the examination and things to avoid before the Pap test is obtained), then accurate cytological interpretation can be compromised in the laboratory.

2. Lack of Effective Communication Between the Clinician and the Patient; Failure to Obtain Pertinent Medical and Sexual History and Failure to Provide Pertinent Clinical Data and Risk Factor Information to the Lab

* Accurate interpretation of Pap smears depends to a significant degree on the sexual history and clinical setting. The clinician must take the time and must be knowledgeable and skilled in obtaining an adequate sexual history from the patient. It is important essential history and any pertinent clinical observations are communicated to the cytopathology laboratory before an accurate cytologic diagnosis is rendered.

3. Poor Specimen Collection

* At least 50 percent of false-negative Pap smears may be directly related to suboptimal methods and techniques of collecting the cervical specimen and preparing the Pap smear. "We as clinicians may take a lousy Pap smear. We take it from the wrong place, don't get into the endocervix, and let the specimen dry out." (OB-GYN News, July, 1985). Furthermore, most laboratories fail to provide cumulative feedback and peer comparison data that define and quantify the efficacy of each clinician's Pap smear sampling technique and practice. In fact, some labs are reluctant to report unsatisfactory and/or non-representative Pap smears for fear of offending the clinician and "losing the business".

4. Poor Slide Preparation and Fixation

* A well taken comprehensive cervical-endocervical specimen may be unsatisfactory for cytologic evaluation if the clinician does not prepare the Pap smear correctly. A properly prepared Pap smear in the clinic is just as important as collecting the appropriate sample from the right area of the cervix. Unlike most other specimens sent to the lab, optimal preparation of the Pap smear is entirely dependent on the expertise of the clinician and/or his/her assistant.

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5. Improper Specimen Identification -- No Name on Slide

* The potential for incorrect identification and mix-up of cases exists if the patient's name is NOT written (in pencil) by the clinician on the frosted end of the slide. Too many cases are processed at any one time to safely leave to laboratory personnel the responsibility of writing the patient's name on each slide. It is the clinician's responsibility to write the name of the patient on the frosted end of the Pap smear slide in order to maintain correct specimen identification and avoid misidentification.

6. Misunderstanding of Pap Smear Results from the Lab and No Verbal Communication with the Pathologist/Cytologist

* The "class" or number system is outdated, and when used without a narrative (descriptive) diagnosis it can lead to great confusion and inappropriate medical care for the patient. A disease cannot be classified in numbers! A diagnosis in a standardized narrative form enables the clinician to fully comprehend cytologic diagnostic findings. Narrative reports eliminate misunderstandings, particularly notable among various pathologists/laboratories that use different classes (numbers) for the same diagnosis. Ideally, every cytologic diagnosis should predictably have its morphologic appearance in the colposcopic and biopsy interpretation. Clinicians should no longer support the number system; they should demand narrative descriptive diagnoses from the pathologists/laboratories.

7. Failure to Follow Cytology Lab Recommendations

* Some clinicians do not follow the lab's recommendations for patient follow-up. If the pathologist is well informed about the cytology/colposcopy practices in the community, s/he can be a valuable and credible consultant concerning follow-up recommendations. When the informed pathologist is supported by established patient care protocols and a computerized patient database and recall system, these medical recommendations initiate automatic patient recall reminders for the clinician, eliminating potential oversight in a busy clinical practice.

8. Failure to Notify Patient of Abnormal Findings/Report or Poor Communication with the Patient

* When a clinician has performed a Pap smear and the results indicate the patient is suffering from an abnormal condition of the cervix, the clinician must take all reasonable steps to inform the patient of the results. On the other hand, the patient is responsible for providing the clinician with enough

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information and cooperation to enable communication to take place. The clinician must clearly state the problem so that the patient understands the implications of the cytological findings and what the next step is.

9. No Provision for Pap Smear Call and Recall Schedule for Women with Normal Results and Confusion Concerning Appropriate Screening Intervals

* Many clinicians and most laboratories fail to provide a call schedule and automatic reminders for patients when a Pap smear test is due, and NOT all patients receive clear guidance from their clinician concerning the frequency of Pap smear screening. Furthermore, clinicians may have incomplete knowledge and may be ignorant about the relative risk of individual patients. Without recommendations and advice from their clinician, some patients will inappropriately accept the guidelines of the American Cancer Society - every three years - when, in fact, they are at high risk and need annual or more frequent Pap smears.

10. Failure to Aggressively Follow-Up Non-Compliant Patients with Abnormal Pap Smear Results

* It is important that at least three attempts are made to contact a patient with an abnormal Pap smear before she is discharged from follow-up. This should be a combination of phone calls - at two different times a day - and letters. These attempts should be documented in the patient's clinical record. The last letter should be certified/return requested. If contact with the patient is made, the importance of immediate follow-up and the implications of delayed follow-up need to be clearly stressed.

11. Failure to Identify Severity & Extent of Cervical Lesions with Colposcopy

* Instruction in colposcopic technique is an integral part of most residency training programs in obstetrics and gynecology, however, in the majority of laboratories no cumulative statistical informational physician feedback loop exists for evaluating the degree of correlation (accuracy) between colposcopic appearances and biopsy/histologic interpretation. Appropriate therapy must be selected based on the skill of the colposcopist plus a reliable pathologic examination (the gold standard) to determine the severity and extent of cervical disease. Unless colposcopy is correctly performed and macroscopic observation is optimal, the pathologist may not receive biopsies from the "worst" part of the lesion and/or from those areas that are responsible for the abnormal cells seen on the Pap smear.

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12. Inappropriate Treatment of Cervical Disease

* If the extent of severity (grade) of a cervical lesion is underestimated, conservative outpatient therapy may postpone correct and definitive treatment and eliminate the opportunity for cure because of unsuspected invasive cancer. Less experienced colposcopists would do well to remember that most cases of invasive cancer after ablative treatment are associated with inadequate colposcopic evaluation and failure to perform an ECC - endocervical curettage.

13. Inadequate Patient Post-Treatment Follow-Up

* A reasonable post-treatment follow-up protocol for CIN (cervical intraepithelial neoplasia) and HPV (cervical condyloma) is a combination of colposcopy and cytology and, if appropriate, histologic examination at three to four months and again at six to eight months following treatment. If residual disease is present, it should be discovered in the majority of patients during one or two of these examinations.

14. Unawareness of Shortcomings and Pitfalls in Pap Smear Testing

* Significant improvement in Pap smear testing will take place when clinicians recognize that the Pap test, unlike any other laboratory examination, is a consultation by the cytotechnologist and pathologist to the clinician who are acting in behalf of the patient. The Pap smear examination is very labor intensive. It is an exacting job, requiring a qualified/certified cytotechnologist to evaluate tens of thousands of cells on a well-stained adequate smear to determine if any abnormality exists. Clinicians must learn how to scrutinize a lab's performance and look beyond immediate economic issues and/or channel allegiance - "the good ole boy network" - before selecting a lab in behalf of their patients.

15. Failure to Initiate a Meaningful Pap Smear Screening Contract with the Pathologist/Laboratory

(See attached sample contract)

16. Inability to Discriminate Between Good and Bad Cytopathology Laboratories - No Selection Criteria Established for Clinicians

(See attached questionnaire)

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17. Using Commercial Pap Smear Labs at Great Distances from the Clinic Without Assessment of the Lab's Competence; Believing All Labs Equally Perform the Pap Test Examination

* Many clinicians who use distant labs do so because of price. Clinicians who are most sensitive to price must understand the "industry" they are supporting. In order to remain competitive and profitable, laboratories screening large quantities of Pap smears at a very low price must: (1) cut down the amount of screening time per slide, (2) avoid or circumvent more expensive (high overhead) quality control procedures (designed to prevent diagnostic errors), and (3) eliminate or sharply reduce continuing cytology education. Unlike an automated, minimally labor-intensive hematology analyzer, capable of accurately performing several thousand CBC's in a 24 hour period, every Pap smear must be examined by a cytotechnologist, who spends on the average, five minutes per slide. Slides with abnormal cells may take much longer to examine. The question a clinician must ask, "am I willing to give a $2.54 answer to a woman whose life or reproductive function may depend on the Pap smear result?" You get what you pay for!

18. Failure to Recognize the Benefits of Using a Local Cytopathology Laboratory

* Since cervical cancer and precancer and genital HPV are infectious diseases of coital origin, preventive measures may be best achieved through public health education. Public health education is most effective in the clinician's office through one-to-one patient education. Clinicians however, must first become informed about community health/disease patterns. A "local" cytopathology laboratory can become a powerful partner in supporting a clinician's practice by providing an "electronic healthcare network" and a knowledge base; i.e., information about the natural history of HPV and CIN, and where and how often the disease occurs. Fundamentally, the "local" cytopathology laboratory provides a pivotal point for improved communication between patient, clinician, pathologist, third party payors, employer, and local public health authorities. Improved communication in the health care sector means better patient care and protection from disease, while at the same time controlling burgeoning medical costs.

Using a "local" cytopathology laboratory will result in fewer broken, lost and damaged Pap smears occurring during transit over long distances. The "local" cytopathology laboratory is also better able to communicate with clinicians who are nearby, particularly when it is so important to correlate Pap smears with colposcopically-directed biopsy results. With this correlation cytotechnologists and pathologists quickly learn to "fine tune" their Pap smear diagnoses, and gynecologists are able

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to improve their colposcopic diagnostic accuracy. The "local" cytopathology laboratory can also work in concert to develop an ongoing, aggressive follow-up Pap smear protocol for high risk women living in the community.

19. Failure to Educate Patients about Genital Human Papilloma Virus Infection, Venereal Transmission of Cervical Cancer, and CIN Prevention

* Cervical cancer is a preventable infectious disease of coital origin. Physicians working in cooperation with concerned groups and the media must educate patients about risk factors: (a) human papilloma virus infection, (b) the high-risk male, (c) promiscuity, (d) non-barrier contraceptive methods, (e) smoking, (f) DES exposure, (g) immune suppression, (h) not having regular Pap smear evaluations and checkups.

20. Failure to Initiate Contact Tracing of Male Consorts of Women with Genital HPV and CIN

* The epidemiologic evidence implicating cervical cancer and precancer as an infectious disease of coital origin - a sexually transmitted disease - compels physicians to rethink traditional protocols for treating women with cervical cancer and precancer. It seems reasonable that vigorous attempts should be made to control this highly contagious and potentially lethal disease by contact tracing of male consorts of women with genital HPV and CIN.

21. Failure to Adequately Evaluate and Treat Males with Genital HPV

* Regrettably, many clinicians are still unaware of the clinical work-up, diagnosis, and treatment of males potentially infected with genital HPV. Not unlike other sexually transmitted diseases, effective control of CIN and invasive cervical cancer will occur when men and women receive and follow public health recommendations for containing the spread of genital HPV.

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FAILURES OF CERVICAL CANCER SCREENING IN THE U.S.

PATIENT PERFORMANCE FACTORS:

1. Inability to Access Public Health Information; Lack of Awareness of the Advantages of Being Screened; Lack of Understanding Concerning the Venereal Transmission of Cervical Cancer
2. Confusion Concerning the Appropriate Pap Smear Screening Intervals
3. No Proactive - "take charge" - Role in Health Care Decisions
4. Reluctance to Talk to Clinician About Sexual History and Cervical Cancer Risk Factors
5. Inadequate Preparation for the Pap Test
6. Ignorance Concerning Abnormal Test Results and Lack of Compliance to Medical Recommendations or NOT Obtaining a Second Opinion
7. Avoidance of the Health Care System -- Fear of Cancer; Fear of Pain; Fear of Hysterectomy; Lack of Insurance Coverage
8. Lack of Awareness of the Inaccuracies of Pap Smear Testing; Inability to Discriminate Among Health Care Providers; Trusting the Medical "System"

CLINICIAN PERFORMANCE FACTORS:

1. Inadequate Pap Smear Test Preparation Instructions to Women
2. Lack of Effective Communication Between the Clinician and the Patient; Failure to Obtain Pertinent Medical and Sexual History and Failure to Provide Pertinent Clinical Data and Risk Factor Information to the Lab
3. Poor Specimen Collection
4. Poor Slide Preparation and Fixation
5. Improper Specimen Identification -- No Name on Slide
6. Misunderstanding of Pap Smear Results from the Lab and No Verbal Communication with the Pathologist/Cytologist
7. Failure to Follow Cytology Lab Recommendations
8. Failure to Notify Patient of Abnormal Findings/Report or Poor Communication with the Patient
9. No Provision for Pap Smear Call and Recall Schedule for Women with Normal Results and Confusion Concerning Appropriate Screening Intervals
10. Failure to Aggressively Follow-up Non-Compliant Patients with Abnormal Pap Smear Results
11. Failure to Identify Severity & Extent of Cervical Lesions with Colposcopy
12. Inappropriate Treatment of Cervical Disease
13. Inadequate Patient Post-Treatment Follow-up
14. Unawareness of Shortcomings and Pitfalls in Pap Smear Testing
15. Failure to Initiate a Meaningful Pap Smear Screening Contract with the Pathologist/Laboratory
16. Inability to Discriminate Between Good and Bad Cytopathology Laboratories - No Selection Criteria Established for Clinicians
17. Using Commercial Pap Smear Labs at Great Distances from the Clinic without Assessment of the Lab's Competence; Believing All Labs Equally Perform the Pap Test Examination
18. Failure to Recognize the Benefits of Using a Local Cytopathology Laboratory
19. Failure to Educate Patients about Genital Human Papilloma Virus Infection, Venereal Transmission of Cervical Cancer, and CIN Prevention

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20. Failure to Initiate Contact Tracing of Male Consorts of Women with Genital HPV and CIN
21. Failure to Adequately Evaluate and Treat Males with Genital HPV

LABORATORY PERFORMANCE FACTORS:

1. Slides Broken/Lost in Transit or in the Lab
2. Unlabeled Slides Separated From Requisition and Mistakes with Accessioning
3. Improper Staining/Coverslipping of Pap Smears
4. Poor Working Environment or Home Screening -- Pap Smears that are Taken Out of the Lab and Screened at Home by Cytotechnologist(s)
5. Cytotechnologist's Lack of Patient's History, Risk Status, and Lack of Availability of Previous Slides and Reports
6. Errors in Cytologic Screening, i.e., Lack of Professional Experience, Lack of Immediate Professional Consultation, Excessive Workloads, etc.
7. Failure to Report Inadequate and Non-Representative Specimens and Failure to Provide Feedback to the Clinician About Cervical Sampling and Slide Preparation Techniques
8. Recording and Transcription Errors
9. Failure to Use Narrative Descriptive Cytologic Diagnoses
10. Errors in Histologic Interpretation and Diagnosis
11. Failure to Correlate Cytology with Colposcopy and Histology
12. Lack of Abnormal Case Follow-Up
13. Pathologist's Deficiencies; i.e., Lack of Formal Training in Cytopathology, and Lack of Availability for Supervision, Consultation and Education
14. Lack of Continuing Medical Education in Cytopathology, and Lack of Familiarity with the Gynecologic Oncology Literature
15. Lack of "Real Time" Quality Control
16. Lack of Quality Assurance Validation for Periodic Review
17. Lack of a Meaningful Written Pap Smear Screening Contract Between the Pathologist and the Clinician

MISCELLANEOUS FACTORS:

1. Failure of Patient Tracking and Clinical Outcome Assessment
2. Biologic Variability of Cervical Lesions
3. Lack of Regulation in the "Cervicology Industry"
4. Lack of Standardized Pap Smear Screening and Reporting
5. Failure to Initiate a High-Risk Male Screening Program and Contact Tracing for Genital Human Papilloma Virus Infection
6. No Requirement for Reporting of Genital HPV and CIN to Local Public Health Authorities

SOLUTIONS:

1. Education and Heightened Awareness of the Pitfalls in Cervical Cancer Screening for Physicians, Patients, Employers, Third Party Payors, Malpractice Insurers, Regulatory Agencies, Professional Societies, and Women's Healthcare Organizations
2. Early Identification of High-Risk Women in the Screening Process Through a Computer Database Maintaining Historical File and/or Current Clinical Information Provided on the Pap Smear Requisition Form

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3. Improved Endocervical-Cervical Sampling by Clinicians
4. Improved Working Conditions for Cytotechnologists; e.g., Standardized Screening Workloads, a Quiet Environment with Suitable Space and Adequate Lighting, Easy Access to Previous Pap Smears and Reports, and More Effective Communication with Pathologists and Clinicians
5. Specimen Quality Analysis on Every Pap Smear Report
6. Medical Recommendations Using Standard State-of-Science Protocols
7. Standardized Narrative Descriptions and Better Communication Between Patients and Clinicians and Cytopathology Laboratories
8. Automatic Follow-up and Case Management for Patients
9. Automatic Follow-up Monitoring with Prompts and Fail-Safe Alerts for Clinicians Confronted with Non-Compliant Patients to Promote Appropriate Clinical Activity
10. Quality Performance Feedback to Lab and Clinician
11. Cumulative Reports for Clinician's Self-assessment of Pap Smear Sampling Techniques and Practice Epidemiology Statistics
12. Pap Smear Reminder Notices for Patients with Accompanying Pap Test Preparation Instructions
13. Patient Follow-up Beyond Control of Individual Clinician; i.e., Laboratory Initiated Patient Recall/Reminder Notices by Computer Database
14. In-house "Real Time" Quality Control and External Quality Assurance to Promote Satisfactory Patient Outcome, to Meet Regulatory Agency Requirements, and to Reduce Medical Malpractice* -- Monitor the Effectiveness and Efficiency of Screening for Cervical Cancer
15. Colpocytohistologic Correlation for Optimal Patient Management
16. Patient Educational Materials
17. "cyto-logic" Newsletter for Education of Clinicians and Staff
18. Clinical Cytology Manual for Clarification and Education of Clinicians, Pathologists, and Cytotechnologists
19. National Performance Standards for Pap Smear Testing Actively Maintained by Networking Laboratories
20. Initiate High-Risk Male Screening Program for Genital Human Papilloma Virus and Increase Awareness of the "Carcinogenic Penis Syndrome" -- Contact Tracing of Male Consorts of Women with Genital HPV and CIN
21. Establish Uniform Cervical Cancer Screening Policy
22. HPV and CIN Should Be Reported as a Sexually Transmitted Disease to Local Public Health Authorities
23. Clinicians Must Be Able to Discriminate Between Good and Bad Cytopathology Labs by Using Appropriate Selection Criteria.
24. Pap Smear Laboratories and Clinicians Should Establish a Meaningful Written Contract Detailing Mutual Responsibilities
25. Database Medical Management System to Carry Out Research into the Natural History and Epidemiology of HPV and CIN
26. Interactive Videodisc Cytopathology Education for Cytotechnologists and Pathologists

*See ACCU-PAP Systems Quality Validation Program and Requirements for Quality Assurance Disclosure

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Microinvasive Cervical Cancer After Five Negative Papanicolaou Smears

Y. EROZAN, MD, N. B. ROSENSHEIN, MD, T. H. PARMLEY, MD, AND
J. D. WOODRUFF, MD

In view of the controversy regarding the appropriate frequency for cytologic screening, a 28-year-old woman who developed microinvasive carcinoma of the cervix less than one year after her fifth negative Papanicolaou smear is described. The lesion was found not high in the endocervical canal, but at the squamocolumnar junction well out on the portio of the cervix. This case documents that the risk of less frequent screening is not zero. ***(Obstet Gynecol 62:82S, 1983)***

In view of the controversy regarding the proper frequency of routine cytologic screening, the authors found it worthwhile to describe the following case.

Case Report

A nulliparous 23-year-old white woman was first seen in January 1976, at which time a routine Papanicolaou smear was negative. She had subsequent negative smears 6, 19, 32, and 42 months after the initial cytology. During this time she was treated for two urinary tract infections and one episode of vaginal candidiasis. Nine months after the fifth negative smear, a routine Papanicolaou smear was interpreted as denoting moderate atypia. The patient was evaluated with a repeat cervical cytology, colposcopy, and directed biopsy. The repeat smear again showed moderate atypia. The colposcopy demonstrated a focal lesion that involved the anterior and posterior cervix but was believed to represent no more than moderate atypia. The colposcopic examination was easily performed with complete visualization of the entire transformation zone. Biopsies taken within the focal lesion were interpreted as moderate epidermoid atypia (cervical intraepithelial neoplasia [CIN] II) from the posterior cervix and marked atypia (CIN III) from the anterior cervix. Cryosurgery and conization were explained to the patient. She elected to undergo sharp conization, although the authors would normally have treated her with less aggressive therapy. Pathologic examination of the sharp cone revealed no disease in one quadrant, CIN III in two quadrants, and microinvasive disease to 2 mm in the fourth quadrant (Figure 1). The margins of resection were ample.

Discussion

At the time of the conization, the patient was 28 years old and had been taking oral contraceptives for nine years. She gave a history of five sexual partners and first intercourse at age 19.

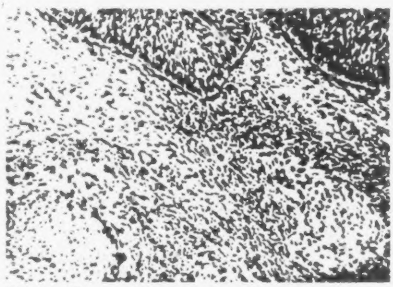

Figure 1. Two foci of microinvasive carcinoma lie beneath a surface of CIN III. The native squamous epithelium is out of the picture, immediately to the right.

The single focus of microinvasion was not high in the endocervical canal, but lay immediately beneath the junction of the transformation zone and the native epithelium in an easily accessible position, well out on the portio. It did not constitute early stromal invasion but rather microcarcinoma without apparent continuity with the overlying epithelium. The patient subsequently underwent a hysterectomy with pelvic node sampling which demonstrated no additional disease.

Obviously, this isolated case provides none of the quantitative data required for making policy decisions about screening frequency. However, it does illustrate that if it is finally determined that the American health care system cannot afford routine annual screening, less frequent screening will be costly to some.

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CERVICAL CANCER AFTER NEGATIVE PAPANICOLAOU SMEARS

To the Editor

The article, "Microinvasive Cervical Cancer After Five Negative Papanicolaou Smears," by Erozan et al, September 1983 (OBSTET GYNECOL 62:82S, 1983), describes a single case in which a 28-year-old white woman was diagnosed as having microinvasive cervical cancer. After five negative Papanicolaou smears, the sixth showed moderate atypia. A seventh smear, a repeat of the sixth, revealed the same moderate atypia. On the basis of this single case, the authors conclude that lack of frequent screening "will be costly to some (patients)."

Although there is great value to reporting a single case of this type, we cannot agree with the conclusion that the frequency of screening is the primary emphasis for early detection and treatment of cervical cancer. The case history itself does not support this conclusion.

1. The patient was in a high-risk group with five sexual partners reported during nine years of sexual activity, and a history of two urinary tract infections and one episode of vaginal candidiasis.
2. The physician was following the patient closely in spite of repeated negative Papanicolaou smears—six Papanicolaou smears done during the 51-month medical history.
3. It was not the frequency of Papanicolaou smears that led to the diagnosis, but good medical practice using a range of diagnostic modalities.

One of three women with cervical intraepithelial neoplasia remains undiagnosed after a single Papanicolaou smear using commonly accepted techniques of sampling, smear preparation, and screening.[1] The most critical question for these women is not how long an interval will elapse before the next cytologic screening, but why the standard Papanicolaou smear screening is not adequate to alert the clinician to the presence of a lesion at the first visit?

Many of the factors that influence the current high rate of false-negative smears can be identified by the cytology laboratory.[2] Each year, millions of Papanicolaou smears are submitted for evaluation, which reflect less than adequate cervical-endocervical sampling[3]; yet physicians, unaware of the quality of the specimen on which the assessment is made, treat patients as if each Papanicolaou smear is a perfect specimen of its kind. Laboratories that make cytologic diagnoses on suboptimal specimens, without reporting back to the physician on the quality (diagnostic reliability) of the smear, are perpetuating the status quo. Under these conditions, is there any assurance that after one false-negative report, the next Papanicolaou smear submitted will result in a more accurate cytologic diagnosis? Dr Erozan and his colleagues have oversimplified the issue by concluding that frequent testing can compensate for the insensitivity of Papanicolaou smear testing as it is practiced today. Instead, the case cited is additional evidence of the urgency to improve 1) the sampling method and technique, 2) the clinician's preparation of the Papanicolaou smear, 3) interpretation and reporting of findings, and 4) communication between the laboratory and physician as to their level of confidence in the cytologic assessment.

Successful cytologic practice requires the cooperation of patient, clinician, pathologists, and cytotechnologist, each of whom must know and follow the guidelines for optimal Papanicolaou smear screening. The harsh reality that has not yet penetrated the consciousness of clinicians is that we must maximize the effectiveness of fewer health care dollars, and must provide the greatest possible value to the patient who depends on the medical system for accurate screening and diagnosis. We can no longer compensate for a high rate of false-negative Papanicolaou smears by more frequent physician visits and repeated screenings.

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Senator **Adams**. Ms. Ashton?

Ms. **Ashton**. Thank you, Senator Adams and Senator Mikulski.

I am a cytotechnologist, registered by the American Society of Clinical Pathologists, with 20 years of experience in the field. The most important thing for me to accomplish in this brief time is to tell you who cytotechnologists are, what their responsibilities in the cytopathology laboratory are, and about some of the economic factors which may influence their performance in the laboratory.

Cytotechnologists are highly-trained professionals who evaluate cellular specimens from all body sites for the detection of disease, most significantly, cancer. The most frequently-encountered cellular specimen is the Pap smear.

The microscopic evaluation of the Pap smear, sometimes referred to as "screening", is the most important function of the cytotechnologist. The process involved with performing this task is labor-intensive and requires the utmost concentration to ensure accuracy.

It is estimated that there are in excess of 5,000 cells on a minimally acceptable cervical smear, and that 94,900 decisions must be made to separate the cell population into good and bad. This is not a passive activity. It is a deliberate, energy-consuming mental process, and at present, there is no automated method or machine to do this test.

What constitutes this evaluation? It is not by holding an unstained slide up to the light as depicted in this week's issue of Newsweek with the caption, "Looking for Subtle Cell Patterns, Lab Technician Studies a Test Slide."

Each of the thousands of cells on the slide must be assessed. This is accomplished by systematically looking at every microscopic field in an orderly fashion. Cytotechnologists look for specific abnormal features which make them stop and more carefully examine cells containing these features.

In addition, they must recognize the changes associated with sexually-transmitted diseases such as human Papilloma virus, mentioned by Dr. Hasselbrack.

After reviewing the entire slide, they must formulate a diagnostic interpretation on the basis of the cellular findings and the clinical information provided. If negative or normal, the findings are reported. If abnormal, the case is reviewed by a pathologist, who makes the final diagnosis.

The ability of the cytotechnologist to perform this deliberate, careful examination of Pap smears may be compromised in the large-volume laboratories or "Pap mills". Some laboratories literally give away their cytology services in order to attract the lucrative clinical laboratory samples, or charge the clinicians, those who collect the cellular sample, as low as $1.50 per case and still expect to make a profit. Many process hundreds of thousands, or even millions, of Pap smears per year.

How does all this affect the cytotechnologist? Well, cytotechnologists' labor is the most expensive part of the operation, and simple mathematics show that in order for these low-cost laboratories to generate a profit, the cytotechnologist must produce large numbers of results.

In addition, by promising 24- to 48-hour turnaround time from receipt of specimen to reporting of results, the cytotechnologists are also pressured to review large numbers of slides.

Financial incentives are offered by the laboratories, and they work. Some pay their technologists by the slide, piecework, at very low rates, sometimes 45 to 60 cents a slide, which makes the cytotechnologist screen literally hundreds of slides per day in order to make a living wage.

Other laboratories pay their cytotechs an hourly wage, but require a daily quota of slides be screened, ranging from 80 to 150 or more, and then provide monetary incentives by paying them per slide for any slides they produce over their quota.

Some are given the opportunity to work on weekends at piecework rates as well. A further incentive to produce results too rapidly is to allow technologists to leave for the day after completing their quota. Some labs allow techs to screen slides at home, even though this is a violation of Medicare and CLIA regulations.

Cytotechnologists are human, and they may succumb to these incentives.

Why do cytotechs work in these environments? Well, they may delude themselves into thinking that they can accurately evaluate large numbers of slides, since their errors have not yet been detected. The incidence of significant abnormality in the general population is low, and it may take years for a cytologic error to be discovered. The patient may have moved away, or the clinician may have changed labs, and the original laboratory may never hear that a patient now has cervical cancer.

Cytotechnologists may also feel that time is on their side; that a lesion missed this year will be picked up next year. But the disease seems to have changed its biologic behavior, and the luxury of having years for detection is no longer available.

Cytotechnologists are concerned patient advocates. But when they are located in a laboratory thousands of miles from the patient and the clinicians as well, they may find it difficult to always remember that they are dealing with a life of another human being, like Barbara.

I can assure you that when a cytotechnologist makes a serious mistake—and we all have made them—they are genuinely concerned. Some have left the field for this reason.

Ms. Thompson stated her preference for testing performed in hospital laboratories. While I do not necessarily dispute this problem, I would like to alert you to the fact that the Medicare personnel standards in independent laboratories are more stringent than those in the hospital laboratory. What is disconcerting, however, is that there is activity under way within the Department of Health and Human Services to reduce the Medicare personnel standards in the laboratory.

I realize that I have illustrated the problems which have already been widely publicized. As a cytotechnologist with 20 years' experience, these problems concern me as much as they concern you. They need to be solved. But nonetheless, they must be viewed in context. The Pap smear still remains a lifesaving cancer detection test.

The American Society for Cytotechnology recommends that a cooperative public/private effort be mounted to find reasonable solutions to the problems and restore the confidence of American women in the reliability of the Pap test.

Thank you for your concern.

Senator ADAMS. Thank you, Ms. Ashton, particularly for your personal explanation of what is occurring. You believe there is widespread publicity, but we find that there is an appalling lack of knowledge of what is really occurring. Your testimony was excellent.

Thank you.

[The prepared statement of Ms. Ashton with an attachment, follows:]

Testimony of Ms. Patricia Ashton
President, Cell Diagnostics, Inc.
Durham, North Carolina
Representing: The American Society of Cytotechnology

"Cancer Detection in Women"
Senate Committee on Labor and Human Resources
January 28, 1988

AS
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ASCT
American Society for Cytotechnology
OFFICE OF THE PRESIDENT

January 28, 1988

POSITION STATEMENT AND RECOMMENDATIONS OF THE AMERICAN SOCIETY FOR CYTOTECHNOLOGY

for distribution at Hearings by Committee on Labor and Human Resources
on Cancer Detection in Women
(Previously distributed to the offices of Senator Dave Durenberger and
Senator William Cohen)

Laboratory Regulation and Performance Monitoring Special Reference to Cytology Laboratories

1. Since its incorporation in 1979, the American Society for Cytotechnology (**ASCT**) has been and continues to be committed to providing its members and consumers with information and recommendations about cytology quality control methods, the value and limitations of Pap smear testing, and regulatory developments which affect the practice of Cytotechnology.

2. Recent media coverage about substandard Pap smear testing, which may have a devastating effect on women who rely on these tests, has highlighted a problem which Cytotechnologists and the **ASCT** have been aware of for many years. The high level of false negative and false positive Pap smears in part result from over-utilized technologists who, because of personal economic necessity, threats of loss of jobs, and pressure to produce for commercial profit, screen hundreds of Pap smears a day in spite of guidelines which recommend considerably lower workloads.

3. The federal government should include guidelines for workloads within its laboratory regulatory system as one method of reducing the number of inaccurate Pap smear results. This is especially important because existing guidelines developed by professional organizations are recommendations only, and are purely voluntary. As such, cytology laboratories may misinterpret or disregard workload recommendations without fear of loss of accreditation or certification status. There is currently no enforcement mechanism to insure compliance with workload guidelines.

4. The **ASCT** is also aware that technologist workload represents but one factor in the quality control mechanisms available to alleviate the problem of inaccurate Pap smear testing. The **ASCT** has developed a Quality Assurance **Criteria Document** that enumerates and evaluates cytology laboratory quality control methods. This document is contained in a recent **ASCT** contract proposal to HCFA (RFP-HCFA-87-0561/CK) for **"Specialized Reviews of Cytology Laboratories"**.

5. The ASCT supports the following federal actions to insure that cytology laboratories receiving Medicare reimbursement for patient testing conform to quality assurance and control guidelines:

   a. Endorse and support studies to determine actual false negative and false positive rates in cytology laboratories, and determine acceptable levels of performance on cytologic tests.
   b. Incorporate the ASCT workload guidelines, with reasonable minimum and maximum limits, into federal regulations governing performance in cytology laboratories.
   c. Develop or support the development and institution of standardized measures of laboratory performance, which may include (1) proficiency testing; (2) clinical correlation studies; (3) uniform diagnostic and reporting methods; (4) patient treatment or follow-up recommendation methods; and/or (5) reliable rescreening mechanisms.
   d. In concert with the ASCT and interested medical organizations, mandate educational programs that insure physicians using cytology services collect satisfactory cytologic specimens and provide clinical history pertinent to cytologic diagnosis.

The ASCT is ready to offer its expertise and services in the fact-finding process, review, monitoring, and development of quality assurance programs relating to cytologic testing. For additional information, the following individuals may be contacted:

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ASCT
American Society for Cytotechnology
OFFICE OF THE PRESIDENT

EXECUTIVE SUMMARY

Cancer of the uterine cervix and the reliability of the Pap smear in providing early detection of this disease is burdened with multifaceted problems involving profit-oriented laboratories, technologist workload and salaries, and collection of an adequate cell sample.

An increasing number of Pap smears are being sent to laboratories where profit marigns are the primary consideration and consequently diagnostic accuracy has suffered. Clinicans are drawn to these operations by low costs and a promise of rapid results. These laboratories are able to make such an attractive offer by paying the cytotechnologists, who microscopically evaluate the Pap smear, very low salaries and pressuring them to review excessively large numbers of slides.

The accurate microscopic evaluation of a Pap smear requires that the cytotechnologist carefully look at every one of the thousands of cells on the slide to detect any abnormal changes. If this examination is rushed, the risk of "missing" abnormal cells increases. On the basis of this microscopic examination, the cytotechnologist must then decide if these changes mean the patient has cervical cancer or one of its precursor lesions. This preliminary diagnosis is then confirmed by a pathologist who must review the abnormal cases and prepare the final diagnostic report. The ramifications of this decision weigh heavily on the health and welfare of all women in this country.

Another factor affecting diagnostic accuracy is the qualifications of the cytotechnologist and pathologist. Cytotechnologists are required to complete a minimum of 12 months in an cytotechnology intensive training program and obtain certification by successfully passing a national registry examination. However, the pathologist, who reviews all abnormal cases detected by the cytotechnologist, may receive as little as 0-3 months of training in cytopathology.

Cervical cancer and its precursor lesions go undetected if the abnormal cells are not removed from the cervix when the Pap smear is taken. Inadequate preservation of the cell sample for transport to the laboratory damages the cells and compromises the accuracy of the microscopic evaluation. Thus good sampling techniques by the clinicians are essential for an optimum specimen.

Low salaries and excessive workloads are causing cytotechnologists to leave the profession and seek more financially rewarding positions. Fewer individuals are entering the field because better working conditions and higher salaries can be obtained in other professions. Thus a declining number of qualified cytotechnologists to review Pap smears further compounds the problem.

Every effort must be made to confront these problems, find solutions and reassure the women of this country that they can comfortably rely on the accuracy of Pap smear testing.

Introduction:

The Pap smear- literally thousands of cells are removed from the surface of the uterine cervix and placed on a microslide. A cytotechnologist or pathologist will microscopically evaluate these cells and will decide if this woman has cervical cancer. This decision is made for thousands of women each year in this country.

Factors which determine if women will receive an accurate diagnosis and will be discussed in this testimony include the following: (1) responsibilities of the cytotechnologists in the laboratory, (2) how the microscopic evaluation is made, (3) qualifications of cytotechnologists and pathologists, (4) excessive workloads, (5) inadequate salary levels for cytotechnologists, (6) profit-oriented laboratory administrations, and (7) clinical factors affecting Pap smear testing.

Problems in each of these areas are contributing to the laboratory error rates recently brought to public attention. A concerted effort from appropriate medical professional organizations and legislative groups will be required to eliminate these problems and ensure that every woman in this country receives an accurate diagnosis on her Pap smear.

Responsibilities of the Cytotechnologist

When Pap smears are received in the cytology laboratory, the cytotechnologist stains them to distinguish the two major parts of the cell- the nucleus and the cytoplasm.(Figure 1) The staining solutions must be replenished daily or they will not penetrate the cells properly and the microscopic evaluation will be impaired. In some laboratories where the primary consideration is keeping costs at a minimum, old and dirty solutions are used which compromises diagnostic accuracy.

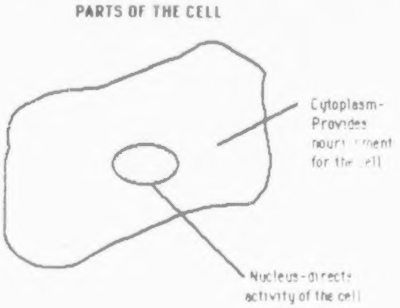
PARTS OF THE CELL
Cytoplasm-Provides nourishment for the cell
Nucleus-directs activity of the cell

Figure 1

Following the staining procedure, the cytotechnologist microscopically evaluates each slide examining thousands of cells looking for any abnormal changes. The detection of these abnormal cell changes rests solely with the cytotechnologist. The second reviewer, the pathologist, only examines the abnormal cases found by the cytotechnologist. Thus the responsibility for patient welfare accepted by cytotechnologists is a tremendous one.

Cytotechnologists must not only detect abnormal cell changes but must also be able to interpret what they mean in terms of the clinical history of their patients. For example, what risk factors for cervical cancer have they been exposed to; are they at risk for other types of female genital tract cancers; what medication or therapy has a patient received which may alter the appearance of the cells; and what patients are at risk for recurrent cancer?

The cytotechnologist must ultimately merge the clinical information and cell changes into preliminary and final diagnoses. Because these diagnoses determine whether a patient has cancer, many laboratories conduct quality control programs to assure a high degree of diagnostic accuracy is being maintained. A certain percentage of the cases in which the cytotechnologists have found no clinically significant cell changes are reviewed by supervisory cytotechnologists or pathologists. If cases are found with significant diagnostic errors, the clinician will be notified immediatedly and the patient will return for re-examination and follow-up. Again, there are no regulations which enforce quality assurance practice in *every* cytology laboratory.

The cytotechnologist is often responsible for obtaining the diagnoses made on any tissue removed from their patients and determining the degree of cytology correlation. Low correlation rates will spark an investigation to determine if the problem lies in diagnostic accuracy or inadequate sampling of either the cytologic or histologic specimen.

How the microscopic evaluation is made:

The cytotechnologist must examine each cell on the slide to determine if there are any changes in cell shape, nuclear size and shape, and arrangement and size of the nuclear contents.(Figure 2) They systematically cover every area of the slide with overlapping fields in order to make sure every cell is evaluated. In a symposium published in *Laboratory Medicine*,1983, Clark states "that there are approximately 5225 cells on a minimally acceptable cervical smear and that 94,900 decisions must be made to separate this cell population into good and bad."(see Appendix A) The cell in Figure 2 has normal features: the cell shape is uniform; the nuclear size is small and the shape is round; the nuclear contents (DNA or chromatin) are small and evenly arranged.

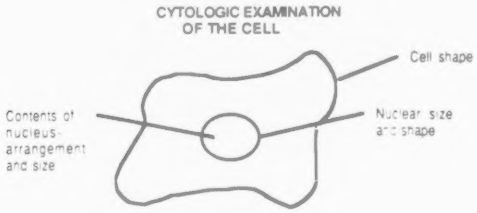

Figure 2

The cytotechnologist must recognize mild changes as seen in Figure 3. The nucleus is enlarged which means the cell is responding to a stimulus. The cytotechnologist must know what all these various stimuli are and closely examine the slide to determine if the reaction is clinically significant such as that caused by the presence of a microorganism. Detecting cellular changes related to certain sexually transmitted agents such as the Human Papilloma Virus (HPV) is extremely important as certain strains of this virus are associated with the development of cervical cancer.

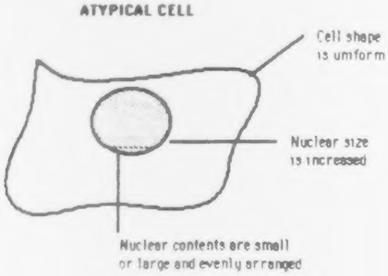
ATYPICAL CELL
Cell shape is uniform
Nuclear size is increased
Nuclear contents are small or large and evenly arranged

Figure 3

Perhaps the most significant cell change that must be recognized by the cytotechnologist is the "dysplastic" cell represented in Figure 4. The nuclear size is greatly increased and the nuclear contents are enlarged. This change is a major warning signal that the cells now have the potential to continue changing and can ultimately transform to invasive cervical cancer. Detecting dysplasia catches the process in a "pre-cancerous" state and removal of these lesions eliminates the immediate threat of cervical cancer to these patients. However, continued exposure of the epithelium to certain sexually transmitted diseases such as HPV, virtually assures a recurrence of dysplasia. If the dysplasia goes undetected, the patient's risk for developing cervical cancer increases significantly.

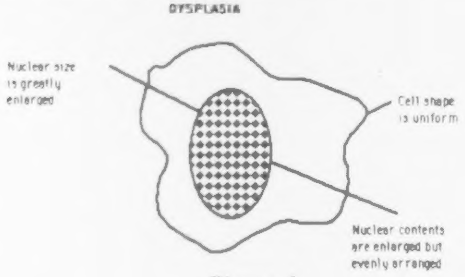
DYSPLASIA
Nuclear size is greatly enlarged
Cell shape is uniform
Nuclear contents are enlarged but evenly arranged

Figure 4

Figure 5 represents the next step in the transformation of "pre-cancerous" epithelium toward an invasive malignancy. The nuclear contents become larger, the nuclear size remains increased, and now the cell shape is lost completely. If detected and treated, the progression to cervical cancer is halted -if undetected, the progression to cervical cancer is inevitable.

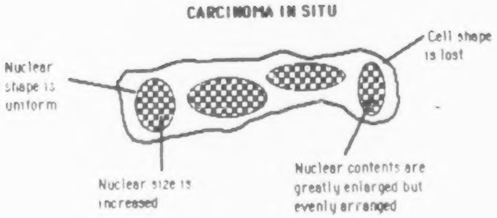
CARCINOMA IN SITU
Nuclear shape is uniform
Cell shape is lost
Nuclear size is increased
Nuclear contents are greatly enlarged but evenly arranged

Figure 5

Figure 6 depicts a cell change representing invasive cervical cancer. The disease is no longer just confined to the epithelial surface, but now has the capability of destroying the uterine cervix by replacing all the normal tissue with cancer cells. These cells also have the ability to invade blood vessels and spread the disease to other parts of the body. Cytologic detection at this point is vital, but the prognosis is not nearly as favorable as it is when the disease is detected in the precancerous stages.

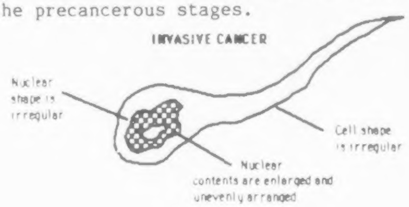
INVASIVE CANCER
Nuclear shape is irregular
Cell shape is irregular
Nuclear contents are enlarged and unevenly arranged

Figure 6

Qualifications of Cytotechnologists and Pathologists

An intensive training program is required to educate cytotechnologists to not only detect abnormal cell changes but to interpret what they mean (render a diagnosis) so the clinician can administer the appropriate therapy.

Hospital-based programs offer one year of training in cytotechnology to students already possessing a bachelors degree. University-based programs offer one or two years of training and a bachelors degree to students who have two or three years of college pre-requisites.

The Essentials and Guidelines of an Accredited Educational Program for the Cytotechnologist mandate an intensely comprehensive curriculum for students. They are required to know the anatomy and physiology of every body system; the histologic and cytologic appearance of every body tissue; every major disease process of the body including risk factors, symptoms, histologic and cytologic appearance, treatment, and prognosis. They examine two to four thousand slides including specimens from actual patients in addition to study set slides and they complete clinical rotations studying in actual cytology laboratories.

Upon successful completion of their training, they are eligible to sit for the National Registry Examination administered by the Board of Registry of the American Society of Clinical Pathologists. Most graduates elect to take the examination and currently the Board of Registry has certified 9,081 cytotechnologists. As of August 1988, candidates for the examination will be required to have a bachelors degree.

Pathologist training in cytopathology ranges widely from none to a three month rotation in the cytology laboratory to a one year fellowship with an experienced cytopathologist. Yet the pathologist makes the final decision on all abnormal cell changes detected by the cytotechnologist. For cytotechnologists, the minimum acceptable training period is 12 months. In many laboratories the cytotechnologists have more formal training and experience than the pathologist.

New information about interpreting cell changes is constantly being published and presented in seminars and workshops. Using this information improves and sharpens diagnostic accuracy. Yet there is no mandatory nation-wide continuing education program for cytotechnologists or pathologists nor are there proficiency tests for every practicing pathologist and cytotechnologist. However, the state of Florida requires licensure and continuing education for cytotechnologists. The state of New York conducts proficiency testing for cytotechnologists and pathologists who examine material from New York state patients.

Excessive Workloads

The microscopic decisions made by cytotechnologists require intense concentration and careful review of each cell on the slide. The cytotechnologist is expected meet two goals - maintain a 100% accuracy rate and maintain a productivity level which enables results to be quickly reported back to the clinician. The biggest and most controversial question is how many slides can the cytotechnologist evaluate and still be accurate. Compounding the problem is that both of these standards are strongly linked to job security.

The American Society for Cytotechnology has examined this problem and recommends cytotechnologists review no more than 90 Pap smears in a day. However, there are no regulations which restrict the number of slides which can be reviewed per day. In California technologists by law may not be required to examine more than 75 one-slide cases or 50 two-slide cases in a work day. However, this does not restrict the cytotechnologist from screening an unlimited number of slides. Many California laboratories have circumvented the regulation by paying their technologists by the slide (piece-work) at an unreasonably low figure ($.45-$.60 per slide) which encourages the cytotechnologist to screen literally hundreds of slides per day in order to make a living wage. This means each slide containing thousands of cells to evaluate will receive no more than 2 minutes of the cytotechnologist's time. This brief review period greatly increases the risk of simply "not seeing" abnormal cell changes or infectious disease agents.

In other situations, laboratories pay their technologists an hourly wage but demand a daily quota of slides to be screened ranging from 80 to 200. In addition, the laboratories provide monetary incentives to their technologists by paying them "per slide" for any slide they produce over their quota. In many instances, cytotechnologists are encouraged to work on weekends at "piece-work" rates as well. A further incentive to produce results too rapidly is to allow the technologists to leave for the day upon completing their quota. Other laboratories pay cytotechnologists yearly bonuses for screening an average of 100 slides per day.

Inadequate Salary Levels for Cytotechnologists

Low salaries received by many cytotechnologists often pressure them to accept part-time positions in addition to their full time employment. Salaries vary geographically but newly graduated technologists earn $12,000 - $22,000. Working two jobs can easily lead to evaluating 100-200 slides per day which jeopardizes diagnostic accuracy. The most dangerous scenario is the cytotechnologist who reviews slides for eight hours during a full-time day position and then goes directly to a part-time position and continues to evaluate more slides. The combination of fatigue along with the large number of slides reviewed greatly increases the risk for diagnostic error. Under-paid cytotechnologists also accept offers to review slides where they are "paid by the case", meaning a greater number of slides reviewed yields a greater number of dollars.

As representatives of the federal government are conducting this investigation, they should be aware that their own Civil Service employed cytotechnologists are among the lowest paid in the country because they are inappropriately classified as technicians and not technologists. The American Society for Cytotechnology and many of its Civil Service members, has attempted to work with the Office of Personnel Management to revise the classification schedule for cytotechnologists. The Office of Personnel Management as well as the Office of the Surgeon General appear to have little interest in such a reclassification.

This inadequate compensation is forcing many cytotechnolgists to leave the profession seeking higher paying jobs. Board of Registry figures show that out of 9,081 cytotechnologists who have received certification only 5,876 are maintaining their registered status and presumably are working. In addition, young people are finding other careers which are more professionally and financially rewarding and thus the number of cytotechnology training programs is rapidly dropping. Again, Board of Registry figures note a 30% drop in the number of cytotechnologists entering the field since 1981. This is creating a critical shortage of qualified professionals to review Pap smears.

Profit-Oriented Laboratory Administrations

Since 1969 we have seen a change of venue from primarily non-profit hospital-based to profit-making independent and large commercial-based operations. Thus the laboratory industry has become a profitable enterprise for these large commercial ventures. They compete with one another for the laboratory business of clinicians, HMOs, clinics, and even hospitals using high-pressured sales pitches, very low prices, discounts for volumes, and unreasonably short turn-around times. Pap smear testing has been particularly abused in these settings where salesmen literally "give away" the cytology services in order to attract the lucrative clinical laboratory samples. These large laboratories process hundreds of thousands and even millions of Pap smears per year.

How does all this affect the cytotechnologist? Since many of these laboratories are charging the clinicians as low as $1.50 per case, are supplying the clinician with slides, Pap smear spatulas, and fixatives, and still expect to make a profit, cytotechnologist salaries suffer. Since cytotechnologist labor is the most expensive part of the operation, simple mathematics will show that in order for these low-cost laboratories to generate a profit the cytotechnologist must produce large numbers of results. In addition, by guaranteeing 24-48 hour turn-around time (from receipt of specimen to sending report) the cytotechnologists are also pressured to review an unreasonably large number of slides.

Some laboratory administrators are primarily concerned with profit margins and do not recognize the investment (time, concentration, qualified personnel) needed for an accurate Pap smear diagnosis. They offer part-time positions in order to keep up with their large volume of work which attracts under-paid full time cytotechnologists, and as mentioned earlier, may offer overtime to their own under-paid staff who may already be reviewing 100-200 slides per day. In some instances, they even permit "screening at home" despite the fact that Medicare and CLIA regulations mandate that all testing must be performed in a licensed facility.

Clinical Factors affecting Pap Smear Testing

Clinicians play a large role in creating the problems which now plague the Pap smear testing industry. They buy into the theory put forth by many of the large laboratories that "bigger is better and cheap is as good as expensive" for Pap smear examinations. Many will switch laboratories monthly for as little as a ten cent difference in price but rarely pass the savings on to their patients. In addition, they demand short turn-around times for the convenience of their office staff whereby a patient's chart can be left unfiled following her appointment until the Pap smear report is returned, instead of having to repull the chart to file the Pap smear report. In cases of impending surgery or high suspicion of abnormality, the need for rapid (24 hour) result reporting is understandable, but not for results from the routine, yearly gynecologic patient.

Many clinicians dictate to the laboratory how the test results should be reported. There is little uniformity in the terminology of laboratories although the professional organizations and the World Health Organization have attempted to establish such uniformity. Most dedicated cytopathology laboratories like to report results using histopathologic terminology rather than the outdated Papanicolaou Class System I-V. Many clinicians demand that a class be given to the results for their ease in patient management.

Pap smear results are reported in at least six different methods which comprises communication. For example, precancerous lesions-probably the most important diagnosis made- can be reported as dysplasia, Cervical Intraepithelial Neoplasia (CIN), suspicious, Class 3 or Class 4. The ramifications of a misunderstanding between the laboratory and clinicians due to differences in terminology could result in action as serious as an unecessary hysterectomy or a patient in need of therapy being left untreated.

The diagnoses of cytotechnologists and pathologists are only as good as the material they receive from the clinicians. If a specimen has an inadequate number of cells from the cervical and vaginal mucosa, or if the specimen is not properly preserved before submission, the laboratory is unable to render a diagnosis with any degree of confidence and accuracy. Conscientious laboratories will report these findings back to a physician when an inadequate or improperly fixed specimen has been received. However, this determination cannot be made until the specimen has been stained and examined under the microscope.

Laboratories are often reluctant to report these findings to their clients since the client may decide to take his business to a laboratory which will render a diagnosis on any material. If the clinicians do repeat the smear, the laboratory may be expected to process the second specimen at no charge to the physician; the physician, however, may charge the patient even though it is neither the patient's nor laboratory's fault that the first specimen was inadequate or improperly fixed. These threats of loss of business may make some laboratcries compromise what they know to be good laboratory practice and the cytotechnologists must go along with the guidelines established by the laboratory in order to maintain their employment.

Physicians do not routinely give their patients the option of having their Pap smears evaluated at a laboratory of their choice. Giving patients this option would wreck havoc with the contractual arrangements established between clinicians and laboratories, but the American Society for Cytotechnology believes women should have this right. The establishment of direct billing from laboratories to patients would remove the financial incentives for physicians to send their smears to low cost laboratories. This has been shown to happen in states which have adopted direct billing regulations.

The problem affecting cytotechnologists and Pap smear testing is obviously very complex. There are no easy solutions. It is clear that some regulatory change is necessary and in addition, the private sector must assume a greater responsibility for policing its own. The American Society for Cytotechnology is very pleased to be a part of these hearings and is most anxious to assist in any effort to improve the quality of this very worthwhile cancer detection tool which so greatly benefits the women of this country.

Editorial

Cytotechnologists are in the midst of an identity crisis. In the 1950s, Dr George N. Papanicolaou drew together a group of cytotechnologists to advise him and others involved in establishing the essentials of the first training program. Their recommendation was that cytotechnology education programs should be at the level of a bachelor's degree. This advice was not taken, and cytotechnology programs became 2 + 1 programs. Although an individual at this level of education is generally designated as a technician, cytotechnologists have always been considered technologists because of the interpretive evaluative component of their duties. From the time these first essentials were established until today, cytotechnologists have been striving for the creation of academic programs that more properly reflect their skill levels.

Historically, the duties of cytotechnologists have been considered to be of narrow scope. As first perceived in the 1950s, their primary duty was to separate the good from the bad, ie, to "screen." However, cytotechnologists have been and will be required to assess and evaluate cellular morphology in relationship to differential diagnoses, symptoms, therapy, prognosis, and the biologic behavior of tumors. This is far more than screening. I have calculated that there are approximately 5,225 cells on a minimally acceptable cervical smear, and that 94,900 decisions must be made to separate this cell population into "good" and "bad." Even though our mental capacities of perception and the "psychomotor" activities in the examination of a cytologic preparation make these decisions appear automatic, they still must be made. Therefore, the commonly used term "screen" is not as passive as it would appear to be, but is a deliberate, energy-consuming mental process.

In his original cytology atlas, Dr Papanicolaou demonstrated the potential application of the cytologic method for all areas of the body. The first application of this diagnostic technique was in the study of the female genital system. Even today this body site is regarded by most people to be the focus of cytotechnologists' work. To a certain extent, this perception is correct because the major caseload in most cytopathology laboratories concerns the female genital system. However, the cytologic method is now applied to specimens obtained from all areas of the body. Not only are natural secretions, washings, and brushings collected for cytologic study, but the fine-needle aspiration technique has brought deep, formerly inaccessible organs within the scope of the cytologic method as well. Cytotechnologists today are required to know much more than the good and bad in a cervical smear, but must also know the anatomic, histologic, pathologic, and cytologic manifestations of disease in all organ systems.

It is no longer feasible for cytotechnology programs to be glorified bench training programs. Programs now must effect a considerable didactic transfer of information to best prepare cytotechnologists for their professional duties. Once again the battle has begun to bring cytotechnology education programs to the bachelor's level. Cytotechnologists are involved in this battle in a different social setting than when the first essentials were drawn up. Society is more organized now, and there must be more documentation to support program requirements and curriculum prerequisites. In the process of developing new program essentials, several surveys have been undertaken. These were in fact field studies to determine exactly what cytotechnologists do and at what level of judgment they perform. The results of these field studies are included in this issue of LABORATORY MEDICINE.

Following these studies is a discussion of their impact upon program curricula. The studies detected several areas that are generally not well covered by most cytotechnology curricula. One major area is management. The field studies disclosed that many cytotechnologists are involved in managerial duties and problem-solving. The long-held view of the cytotechnologist as a person working alone in a corner of the laboratory is not supported by these studies that demonstrate that 78.4% of cytotechnologists work in laboratories employing two or more technologists. In fact, 42.5% work in laboratories of four or more technologists, which necessitates the development of personnel and laboratory management skills.

Also included in this issue of LABORATORY MEDICINE are two articles that set the scene for these studies. One describes the current status of accreditation and certification for cytotechnology. The other explores other aspects of program status, in particular the applicant and student populations of cytotechnology programs. All medical laboratory technology programs are experiencing a decline in the number of applicants. Not only has the number of applicants decreased, but their quality as well.

Frequently, articles appear in LABORATORY MEDICINE and other journals that discuss areas in cytopathology that overlap other disciplines. For example, air dried, Giemsa-stained body fluid preparations from the clinical laboratory may show some unusual cellular morphology that requires cytologic study for possible malignant origin. The preparation techniques used in the clinical laboratories make such interpretation difficult. Frequently, articles are published on infectious diseases in various body sites without mentioning the morphologic characteristics of the causative organisms or the cellular manifestations of the infections. However, great details about serologic and other diagnostic techniques are often given for the detection of the particular disease.

The final article in this symposium series attempts to coordinate the cytopathologic study of certain infectious diseases with other diagnostic techniques used in the clinical laboratory. Hopefully, this article will serve as a gentle hint to authors and technologists that the cellular morphology of infectious disease is a valid, useful diagnostic concept. Indeed, for the diagnosis of such diseases, the cytopathologic method is frequently the desirable diagnostic option.

That the cytologic method can be applied in areas other than cancer detection escapes many professionals. However, the contribution of diagnostic cytology to early detection and definitive therapy for carcinoma and its precursors in all parts of the body has been well documented in numerous publications over the years and is indisputable as well as invaluable.

Last but not least, it is hoped that these articles will demonstrate the extent of skills and the broad scope of knowledge that cytotechnologists must possess in order to perform their duties. Program essentials to be used in cytotechnology education at the bachelor's level have been approved by the American Society of Cytology and will soon be submitted to CAHEA and the AMA. Perhaps a more realistic perception of the field of cytopathology and the duties of cytotechnologists will result from these efforts.

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Symposium

The Practice of Cytotechnology: Part I. Study of the Working Environment

Rhonda Karp, EdD, CT(ASCP), CMIAC, and Mary Claire Jones, MS, CT(ASCP), IAC

A study conducted by Ng in June 1977 and published in 1980,[1,2] reported on certain aspects of the practice of cytology, primarily from the perspective of residency programs and the pathologist. While Ng acknowledged that cytotechnologists are integral to the practice of cytology, he suggested that their practice should be considered separately. The study presented here emphasizes the practice of cytology by cytotechnologists.

Materials and Methods

The intent of this study, conducted under the aegis of the American Society of Cytology, was to gather information about the practice of cytotechnology from the perspective of cytotechnologists and cytopathologists.

Two questionnaires were developed, one to survey cytotechnologists and the other to survey the cytopathologists with whom the cytotechnologists worked. These were pilot-tested to establish content-validity, clarity and readability. Suggestions from the pilot test were incorporated into the questionnaire.

The Sample

Five hundred fifty cytotechnologists were randomly selected by computer from over 6,000 registered cytotechnologists listed by the Board of Registry of the American Society of Clinical Pathologists. This sample size limited the sampling error to less than 10%, based on the Standard Error of Proportion formula.

Each cytotechnologist was requested to return the completed questionnaire, "Questionnaire for Cytotechnologists," in an enclosed, addressed and stamped envelope and to give the other questionnaire, "Questionnaire for Practicing Pathologists," to the pathologist with whom they worked. This method assured that the sample of pathologists would be limited to those who are directly involved in the working environment of the cytotechnologist. While this method of "one-step removed" identification of a sample population (cytopathologists) is rather unusual, survey research consultants confirmed that the uniqueness of the problem warranted proceeding in this manner.

Demographic Variables and Survey Content

Each questionnaire included several questions eliciting demographic information so that the practice environment could be described.

The remaining items on both surveys represented an attempt to gather data related to the specific responsibilities of the cytotechnologists in the areas of diagnosis, sign-out, teaching, research and management. The second part of this article will address the responsibilities of the cytotechnologists; discussion here will focus primarily on the state of the practice environment.

Data Collection

The initial mailing to cytotechnologists included the cover letter, "Questionnaire for Cytotechnologists," "Questionnaire for Practicing Pathologists" and two stamped, addressed envelopes (one for each respondent).

Approximately four weeks after the initial mailing, a three-part, second mailing was undertaken for nonrespondents. The first part was a new cover letter and complete set of enclosures which were sent to those cytotechnologists from whom no response was received. Neither they nor their pathologists had responded. The second part of this mailing was sent to those cytotechnologists who had responded but whose pathologist had not. They were asked in the cover letters to give a duplicate set of materials to their pathologists. The final part of the second mailing was for those cytotechnologists who had not responded although their pathologists had done so. An appropriate cover letter and duplicate set of materials were enclosed.

From Thomas Jefferson University, College of Allied Health Sciences, Philadelphia, PA 19107 and St Joseph's Hospital, Atlanta, GA 30303

Table I: Distribution of Cytotechnologists by Number of Years Working in Cytology

Years Working in Cytology	N	%
1 year or less	11	3.3
2 to 4 years	38	11.5
5 to 7 years	47	14.2
more than 7 years	159	48.0
not presently working in cytology	76	23.0
TOTAL	331	100.0

Table II. Distribution of Cytotechnologists by Number Employed in the Cytology Laboratory

Cytotechnologists in Laboratory	N	%
One	59	21.6
Two-three	98	35.9
Four-five	49	18.0
More than five	67	24.5
TOTAL	273	100.0

Table III: Distribution of Cytotechnologists by Whether They Work with a Pathologist with Special Training or Interest in Cytology

Work with Pathologist with Special Training or Interest in Cytology	N	%
Yes	201	79.8
No	10	4.0
Sometimes	27	10.7
Not at present	14	5.5
TOTAL	252	100.0

Table IV: Distribution of Cytotechnologists by Employment Position

Position	N	%
Staff cytotechnologist	148	59.5
Cytotechnology supervisor	81	32.6
Education coordinator	3	1.0
Other	17	6.9
TOTAL	249	100.0

Results

Response Rate

Four hundred eighty-six letters apparently reached the addressees. A total of 64 surveys were returned to the American Society of Cytology as nondeliverable. Of the 486 delivered responses, 76 (15.6%) of the cytotechnologists indicated they were not presently working in cytology. This meant that the sample of cytopathologists was lowered to 410 because no questionnaire could be forwarded by non-working cytotechnologists to cytopathologists.

The response rate for the cytotechnologist group was 68.1% (n = 331). Of these, 76 or 23% indicated that they were not presently working in cytology and so returned the questionnaire as requested, without responses. A rate of 77% (n = 255) of the responding cytotechnologists returned questionnaires with all or most of the questions completed.

The return rate of cytopathologists was 53.9% (n = 221). Incomplete and duplicate returns were discounted lowering the response rate to 46.3% (n = 190). In the presentation of results which follows, most data for cytotechnologists and cytopathologists are presented in terms of *percentages* since not every respondent answered each question every time. In general the range of response from cytotechnologists was 247 to 255, although for most, the response was 252 or 253. The range for cytopathologists was 182 to 190. Therefore, percentages are used wherever possible to ensure validity in making comparisons between and among items.

Tables I-IV list the number and percentage of responses received to questions about the practice environment from the questionnaire for cytotechnologists. Tables V-XIII summarize the responses received from the questionnaire sent to practicing cytopathologists.

Summary and Discussion

Summary of demographic characteristics reported by cytotechnologists. Almost half (48%) of the respondents have been working as cytotechnologists for more than seven years (Table I). More than half, or 57.5%, work in laboratories of three cytotechnologists or fewer, 21.6% work in laboratories where they are the only cytotechnologist (Table II). While most cytotechnologists (79.8%) reported working with a (cyto)pathologist with special training or interest in cytology, over one fifth (20.2%) reported that this was the case never, only sometimes, or not at present (Table III). Most respondents were staff cytotechnologists (59.5%), but an additional 32.6% were supervisors (Table IV). Those who classified themselves as "other" represented 6.9% of the respondents and included four supervisor/education coordinators, several cytotechnologist/histologists, and a few researchers and instructors.

Summary of demographic characteristics reported by cytopathologists. More than half (56.3%) of the responding pathologists work in private laboratories (Table V) with more than 15,000 cytology cases annually (51.3%) (Table VI). Although most cytopathologists reported signing out daily (55.7%), a large number (41.6%) do so on a rotational basis (Table X). More than half of pathologists (64.9%) work in laboratories employing three or fewer pathologists (Table VIII), and have been in practice longer than 15 years (51.1%) (Table XIII). Most pathologists (79.8%) reported they currently employ the desired number of cytotechnologists, whereas 20.2% reported a need for additional cytotechnologists (Table IX). Most pathologists

Table V: Distribution of Pathologists by Type of Laboratory

Type of Laboratory	N	%
Private	107	56.3
Armed Forces	9	4.7
State, County, Municipal	22	11.6
University and or Medical Center	52	27.4
TOTAL	190	100.0

Table VI: Distribution of Annual Cytology Specimen Volume

Volume	N	%
Less than 5,000	18	9.7
Between 5,000 and 15,000	73	39.0
Between 15,001 and 25,000	38	20.3
Greater than 25,000	58	31.0
TOTAL	187	100.0

Table VII: Distribution of Volume as to Percentage of Gynecologic Specimens

Percentage of Gynecologic Specimens	N	%
90% to 100%	116	62.5
80% to 89%	32	17.2
70% to 79%	19	10.2
60% to 69%	9	4.8
Less than 60%	10	5.3
TOTAL	186	100.0

Table VIII: Distribution of Pathologists by Number Employed in the Laboratory

Pathologists in Laboratory	N	%
One	40	21.1
Two-three	8[illegible]	43.8
Four-five	35	18.4
More than five	31	16.7
TOTAL	188	100.0

Table IX: Distribution of Need for Additional Cytotechnologists

Need for Additional Cytotechnologists	N	%
None needed	150	79.8
Half-time cytotech needed	10	5.3
One full-time cytotech needed	22	11.7
More than one full-time cytotech needed	6	3.2
TOTAL	188	100.0

Table X: Distribution of Pathologists' Sign-out Responsibilities

Sign-out responsibility	N	%
Daily	103	55.7
On a rotational basis	77	41.6
Only on a fill-in basis	3	1.6
Never	2	1.1
TOTAL	185	100.0

(80.6%) have received some continuing education in cytology during the past five years. 19.4% reported no recent continuing education (Table XI). Most (64.5%) received their formal cytology training through cytology courses or workshops, or both (Table XII).

Discussion. There is an often stated belief among cytotechnologists that many of their colleagues (if not they themselves) work with a pathologist with little or no training or interest in cytology. In fact, only 4.0% reported such a situation, with another 5.5% reporting that currently this was the case. An additional 10.7% indicated that they sometimes work with a pathologist with special training and interest in cytology (these respondents were probably those who are employed in a laboratory where the pathologists rotate cytology sign-out responsibility). It is interesting to compare the perceptions of these cytotechnologists to the responses reported by pathologists about their training in cytology and participation in cytology continuing education. Fourteen percent of responding pathologists reported they had no formal training in cytology. Also, 19% of the pathologists reported no participation in continuing education in cytology during the past five years. It would appear that there are cytotechnologists who do work with a pathologist with little or no training or interest in cytology, but they are in the minority.

Information provided here describes the working environment in which the practice of cytology occurs. It confirms some of the initial work in this area[1,2] and also expands it. The distribution and positions of the cytotechnologists and their perceptions as to whether they work with a pathologist with special training and interest in cytology are included. Distribution information on pathologists and data on laboratories are also reported. Although the response from pathologists was less than expected (perhaps due to the unique survey method) comparison of percentages with previous work correlates positively, thus adding to the credibility of this study.

Part II will focus on the study of cytotechnologists' responsibilities from the perspectives of pathologists and cytotechnologists.

References

1. Ng ABP. Current status of practice and training in cytology. I. A survey of the practice of cytology in anatomic pathology laboratories. Am J Clin Pathol 1980; 73:202–216.
2. Ng ABP. Current status of practice and training in cytology. II. A survey of cytology training in pathology training programs. Am J Clin Pathol 1980; 73:217–231.

Table XI: Distribution of Continuing Education as Reported by Pathologists*

Type of Continuing Education	Pathologist N	Pathologist %
National cytology scientific meeting in past 12 months	72	38.7
Local cytology workshop in past 12 months	89	47.8
National cytology scientific meeting in past 5 years	116	62.4
Local cytology workshop in past 5 years	101	54.3
No continuing education in cytology during past 5 years	36	19.4

*More than one answer was recorded by some respondents.

Table XII: Distribution of Types of Formal Training in Cytology for Responding Pathologists

Description of Training	N	%
No formal training	26	14.0
Exposure during pathology residency	40	21.5
Cytology courses	120	64.5
TOTAL	186	100.0

Table XIII: Distribution of Length of Practice for Pathologists

Time in Practice	N	%
Less than 5 years	17	9.3
5 to 10 years	41	22.6
11 to 15 years	31	17.0
16 to 20 years	29	15.9
21 to 30 years	50	27.5
Greater than 30 years	14	7.7
TOTAL	182	100.0

The Practice of Cytotechnology: Part II. Study of Cytotechnologists' Responsibilities

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Part I of this study reviewed demographic data on cytotechnology practice gathered from cytotechnologists and cytopathologists. Part II will focus on data collected from responses to questions regarding practice responsibilities. Each question was composed of several items, all of which are presented in the accompanying tables.

Cytotechnologists' Results

Sign-out. Table I presents the data pertaining to specimens signed out by cytotechnologists which are not reviewed by the pathologist. A point of interest is that 18.6% of the cytotechnologists reported signing out nonnegative, gynecologic specimens either rarely, sometimes, or always. Also, 30.1% of the cytotechnologists reported that they sign out negative nongynecologic specimens without the pathologist's review; 14.5% said they always do so.

Symptomatology, histology, electron microscopy and treatment. Table II illustrates cytotechnologists' responsibility for knowing the significance of symptomatology, histology, electron microscopy, and treatment. Almost one half of the cytotechnologists (44%) are always responsible for knowing the significance of the symptomatology; 47.6% are responsible sometimes or rarely. Histologic slides are reviewed either sometimes or always by 42.8% of the responding cytotechnologists. In addition, a total of 54.3% are always responsible for knowing the significance of various modes of treatment. Taken with the 'sometimes' category, a total of 84.6% are expected to know about the treatment either sometimes or always.

Cytopreparatory responsibilities. A variety of cytopreparatory tasks and the frequencies with which cytotechnologists are responsible for them are reported in Table III. In almost every case, about one third of the cytotechnologists reported that they were always responsible for these tasks. Only in the item regarding specimen collection did the most frequent response drop to the "sometimes" category. In addition, most cytotechnologists have the responsibility of troubleshooting problems with specimen preparation.

Teaching responsibilities. Table IV records cytotechnologists' teaching responsibilities. Before studying the responses, it should be noted that most cytotechnologists do not teach cytotechnology students because in each of the 65 active educational programs, an education coordinator as-

Table I: Distribution of Frequency with Which Cytotechnologists Sign Out Cases Without Pathologist's Review

Types of Cases	Never	Rarely	Sometimes	Always	N.A.*	TOTAL
Negative gynecologic specimens	7.1	2.4	6.3	83.8	.4	100.0
Nonnegative gynecologic specimens	81.0	9.3	8.1	1.2	.4	100.0
Negative nongynecologic specimens	67.6	6.3	9.3	14.5	2.3	100.0
Nonnegative nongynecologic specimens	92.1	1.6	2.8	.4	3.1	100.0
Negative cell blocks	64.4	4.4	4.0	4.7	22.5	100.0
Nonnegative cell blocks	75.8	.8	.8	0	22.6	100.0
Negative fine-needle aspirations	75.1	3.9	3.9	6.0	11.1	100.0
Nonnegative fine-needle aspirations	86.5	1.6	.8	0	11.1	100.0

*Not applicable

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Table II: Distribution of Frequency with Which Cytotechnologists are Responsible for Symptomatology, Histology, Electron Microscopy, and Significance of Treatment

Responsibility	Never	Rarely	Sometimes	Always	N.A	TOTAL
Knowing the significance of symptomatology	8.3	7.8	38.7	44.1	2.0	100.0
Reviewing histologic slides	28.4	24.7	32.7	7.1	7.1	100.0
Electron microscopic correlation	56.8	3.9	2.3	1.2	35.8	100.0
Knowing the significance of various treatment (drugs, radiation) on cells	6.7	6.7	30.3	54.3	2.0	100.0

Table III: Distribution of Frequency with Which Cytotechnologists are Responsible for Various Cytopreparatory Tasks

Task	Never	Rarely	Sometimes	Always	N.A	TOTAL
Troubleshooting problems with preparations	4.9	8.9	25.9	58.3	2.0	100.0
Assisting in specimen collection (gastrics, fine-needle aspirations, etc)	24.1	14.9	30.3	18.0	12.7	100.0
Evaluating new procedures	6.7	17.7	35.0	38.6	2.0	100.0
Implementing new procedures	11.5	16.7	32.5	37.3	2.0	100.0
Developing new procedures	16.1	20.5	30.1	30.9	2.4	100.0
Developing a procedure manual	26.9	16.3	19.2	35.5	2.1	100.0

Table IV: Distribution of Frequency with Which Cytotechnologists are Responsible for Teaching Various Groups

Teaching	Never	Rarely	Sometimes	Always	N/A	TOTAL
Cytotechnology students	31.8	3.6	8.7	8.7	47.7	100.0
Pathology residents	34.3	7.2	12.3	6.0	40.2	100.0
Medical students	36.7	10.7	5.9	3.6	43.1	100.0
Pathologists	41.9	8.5	12.1	2.4	35.1	100.0
Clinicians (eg, specimen collection, uses of cytodiagnosis)	22.8	20.4	28.4	8.8	19.6	100.0
Hospital personnel other than physicians about collection, uses of cytology	18.3	16.6	33.6	14.5	17.0	100.0

Table V: Distribution of Frequency with Which Cytotechnologists are Responsible for Various Management Functions

Responsibility	Never	Rarely	Sometimes	Always	N/A	TOTAL
Personnel (hiring, firing)	62.1	4.7	15.0	8.3	9.9	100.0
Inventory, ordering supplies	25.5	9.6	19.7	42.1	3.1	100.0
Compiling annual reports, statistics	32.4	11.6	16.2	34.8	5.0	100.0
Preparation of budget	60.5	6.7	9.1	17.4	6.3	100.0
Quality control	21.5	5.3	19.5	50.8	2.9	100.0
Developing and reporting, recording methods	29.4	10.3	20.2	35.7	4.4	100.0
Working on implementing computerized systems of reporting, etc	44.9	9.1	10.6	10.2	25.2	100.0

sumes this responsibility. Also, the chances are slim that any one of the several thousand cytotechnologists in the United States works in a laboratory where there is also a cytotechnology educational program. The chances are also slim for cytotechnologists to teach medical students (126 medical schools) and pathology residents. Pathology residents are generally not found in all hospitals in which a laboratory is located. Of significance are the percentages of cytotechnologists who at some time teach clinicians (57.6%) or hospital personnel other than physicians (64.7%).

Management functions. Various management functions and cytotechnologists' involvement in them are shown in Table V. It is important to note that larger laboratories in both hospitals and the private sector [illegible] have centralized many of these [illegible]tions, such as personnel, inventory, and ordering of supplies. A reported 42.1% of the cytotechnologists were always responsible for supplies, or, in adding the "sometimes" category, 61.8% were expected to maintain supplies. More than one third compile the annual reports (34.8%) and develop the reporting and recording methods (35.7%). At least half of the cytotechnologists (50.8%) reported that they were always responsible for quality control.

Research and special techniques. Development of research proposals and their implementation, writing, photomicrography and special techniques are addressed in Table VI. Except for the responsibilities associated with electron microscopy (Table II) and teaching (Table IV), it should be noted that these items elicited the largest number of "not applicable" responses. Photomicrography is the only item for which cytotechnologists responded with any notable frequency, that is, 26.9% of the cytotechnologists are responsible to some degree for this activity.

Cytopathologists' Results

The information which follows is based on the survey responses of the pathologists who were given the questionnaires by cytotechnologists who worked for them. While the ability to generalize from this data is somewhat limited by the (useable) response rate of 46.3% (n = 190), the percentages shown are comparable to those collected elsewhere (Ng, 1980).

As in the cytotechnologists' questionnaire, pathologists were asked to respond to questions about the responsibilities of the cytotechnologists who worked with them. Where appropriate, parallel responses of cytotechnologists and cytopathologists will be noted in the narrative.

Required review of cases by pathologists Pathologists were asked to indicate which categories of cytologic diagnosis required a pathologist's review. The results, shown in Table VII, show that nearly all require review of all gynecologic negatives, all nongynecologic negatives, and all atypical, suspicious or positive gynecologic and nongynecologic cases. Several of the items in Table VII represent the complement to items in Table I. It is important to note that the cytotechnologists responded in a graduated mode, ie, never, rarely, sometimes, always or not applicable, while pathologists were presented with an essentially dichotomous mode, ie, yes or no. Any comparisons, therefore, must take into account this difference in response modes. For example, 14.5% of the cytotechnologists reported that they always sign out negative nongynecologic specimens which complements the 86.3% of pathologists who responded that all negative nongynecologic specimens must be reviewed. A similarly complementary item is the response pertaining to negative gynecologic cases in which 5.8% of the pathologists said review is required and 92.5% of the cytotechnologists said they sign out such cases at some time without review.

Additional diagnostic responsibilities Results of the questions regarding other diagnostic responsibilities expected of cytotechnologists by pathologists are found in Table VIII. Ninety-six of 190 (50.5%) of the responding pathologists expect cytotechnologists to screen and mark cell blocks, while 74 (38.9%) expect them to interpret tissue fragments from aspiration biopsies.

Table VI. Distribution of Frequency with Which Cytotechnologists are Responsible for Research and Special Techniques

Responsibility	Never	Rarely	Sometimes	Always	N/A	TOTAL
Development of research proposals	48.0	9.5	5.8	2.0	34.9	100.0
Implementation of research proposals	44.7	9.4	9.0	2.4	34.5	100.0
Scientific writing, manuscript preparation	46.5	13.1	7.0	2.7	30.5	100.0
Photomicrography	46.2	9.7	10.0	7.2	26.9	100.0
Special techniques (electron microscopy, immunofluorescence, etc.)	51.0	4.0	7.0	4.0	34.0	100.0

Table VII. Frequency of Pathologist's Review of Cytologic Diagnoses

Diagnoses Requiring Review	N	%
All gynecol. negatives	11	5.8
10% of all gynecol. negatives	126	66.3
All nongynecol. negatives	164	86.3
10% of all nongynecol. negatives	12	6.3
All atypical gynecol. cases	171	90.0
Only atypical gynecol. cases more serious than mild dysplasia	16	8.4
All atypical nongynecol. cases	145	76.3
A portion, but not all, of atypical nongynecol. cases	7	3.7
All suspicious cases	168	88.4
All positive cases	168	88.4
(n = 190)		

Table VIII. Frequency of Additional Diagnostic Responsibilities Expected of Cytotechnologists

Additional Responsibility	N	%
Interpretation of tissue fragments from aspiration biopsies	74	38.9
Screening and marking cell blocks	96	50.5
Reviewing and interpreting histology slides	17	9.0
(n = 190)		

Table IX. Minimal Level of Performance Expected From Cytotechnologists

Level of Performance	N	%
Distinguish normal from abnormal only	4	2.1
Separate cases into Classes I to V	73	38.4
Separate cases into negative, suspicious, and positive	9	4.7
Develop a diagnosis in descriptive terminology	104	54.8

Minimal expected performance level As shown in Table IX, over one half of the 104 responding pathologists (54.8%) expect cytotechnologists to develop a diagnosis in descriptive terminology. Another 38.4% (n = 73) expect cases to be separated into Classes from I to V. Note that few pathologists expect only identification of normal abnormal or separation into negative, suspicious, or positive categories.

Disagreement over nonnegative cases Pathologists were asked to report the percentage of nonnegative cases in which they disagreed with the cytotechnologist. As shown in Table X, the highest number of pathologists (50.3%, n = 87) reported disagreement in between 1% and 5% of the nonnegative cases. Between 6% and 10% of the nonnegative cases generated disagreement, comprising another 22.0% (n = 38). Only 13.3% of those re-

Table X: Distribution of Frequency of Disagreement Between Cytotechnologists and Pathologists Regarding Nonnegative Cases

Frequency of Disagreement	N	%
Less than [illegible]	25	14.4
Between 1% and 5%	87	50.3
Between 6% and 10%	38	22.0
Between 11% and 15%	11	6.4
Between 16% and 20%	9	5.2
Greater than 20%	3	1.7
TOTAL	173	100.0

Table XI: Distribution of Standard Procedure in Case of Diagnostic Disagreement

Procedure in Case of Disagreement	N	%
Defer to cytotechnologist's judgment	2	1.0
Rely on own judgment	109	52.9
Seek consultation	54	26.2
Formulate a compromise diagnosis	41	19.9
TOTAL	206*	100.0

*In some cases more than one response was indicated.

Table XII: Distribution of Frequency with Which Cytotechnologists Report Abnormal or Positive Diagnoses Directly to Clinicians

Cytotechnologists Report to Clinicians	N	%
Never	31	17.1
Only after pathologist's review	125	69.1
On rare occasions, prior to pathologist's review	22	12.2
Routinely, prior to pathologist's review	3	1.6
TOTAL	181*	100.0

sponding reported disagreement on more than 10% of nonnegative cases.

Procedure in case of diagnostic disagreement. As illustrated by Table XI, when disagreement occurs over a diagnosis, more than half of the pathologists (52.9%) indicated that the standard procedure would be to rely on their own judgment. However, 46.1% felt the difference in opinion required either a consultation or formulation of a compromise diagnosis.

Report of diagnosis to clinician. Table XII indicates the frequency with which cytotechnologists relate abnormal or positive diagnosis directly to clinicians. Of 181 responding pathologists, 125 (69.1%) report that only after a pathologist's review are cytotechnologists allowed to relate a diagnosis to clinicians. Thirty-one (17.1%) reported that their cytotechnologists never were allowed to relate abnormal diagnoses directly to clinicians.

Comparison of degreed and nondegreed cytotechnologists. One part of the questionnaire for pathologists asked if they had experience with both degreed and nondegreed cytotechnologists. Of the 190 pathologists who responded to this question, 65.3% (n = 124) reported having worked with both. If there was experience in working with both groups, the pathologist was asked to compare the performance of the two groups for several categories. The responses, reported in Table XIII, show that most saw no difference in almost all areas of performance. The greatest difference was reported by pathologists to be in supervisory capability, where 45.9% (n = 55) indicated that degreed cytotechnologists performed better in this category.

Distribution of cytotechnologists' work time. Pathologists were asked to indicate the percentage of time their cytotechnologist spent screening, clerking, preparing specimens, teaching, or performing research and other activities. The results in Table XIV show that 78.5% of responding pathologists reported that their cytotechnologists spend 60% to 100% of their time on screening. Pathologists reported that 71.9% of their cytotechnologists did some clerking and 79.6% did some preparation of specimens. Teaching involves a total of 35.5% of cytotechnologists and 17.7% do some research.

Delegation of responsibility. Pathologists were asked to indicate those areas of responsibility they delegated to their cytotechnologists, and where they assumed it themselves or shared it with the cytotechnologists. The results, illustrated in Table XV, indicate that cytotechnologists were solely responsible most frequently in the area of policy development. In 44.1% (n = 82) of responses, cytotechnologists were reported to be solely responsible for writing the procedure manual. Revision of the procedure manual was the next responsibility most commonly delegated to cytotechnologists (37.1%). Taken as a whole category, sharing responsibilities with cytotechnologists for policy development averaged 53.3%. In a high proportion of the responses, teaching and research responsibilities were not considered applicable (N/A). This is confirmed by the cytotechnologists' high proportion of N/A responses in Tables IV (teaching) and VI (research). For specific responses where wording of cytotechnologists' and pathologists' items were the most similar, the responses were noticeably close. For example, in Table III for "developing new procedures," 30.9% of the cytotechnologists said they were always responsible, while in Table XV for "devise new procedures," 27.4% of the pathologists said that cytotechnologists had this responsibility.

Preparation of the laboratory budget, often viewed as a management function, was a responsibility that is shared with cytotechnologists by 41.4% (n = 77) of the pathologists. In 22.6% of responses (n = 42), cytotechnologists reportedly (according to the pathologists) carried out the proc-

Table XIII Distribution of Responses Comparing Degreed and Nondegreed Cytotechnologists

Performance Area	Degree better		Cert. better		Same	
	N	%	N	%	N	%
Screening ability	24	19.8	5	4.1	92	76.1
Interest in cytotechnology	37	30.6	3	2.5	81	66.9
Technical expertise	35	29.0	6	5.0	80	66.0
Supervisory capability	55	45.9	7	5.8	58	48.3
Attendance	20	16.5	6	5.0	95	78.5
Performance level (general)	35	28.9	7	5.8	79	65.3

(n = 121, except for supervisory capability where n = 120)

Table XIV Distribution of Cytotechnologists Work Time
(Percent of Time)

Duty	1–19%		20–39%		40–59%		60–79%		80–100%	
	N	%	N	%	N	%	N	%	N	%
Screening	0	0	3	2.5	36	19.9	53	29.3	89	49.8
Clerking	98	54.2	30	16.6	2	1.1	0	0	0	0
Preparing specimens	81	44.8	57	31.5	6	3.3	0	0	0	0
Teaching	60	33.2	3	1.7	1	1.6	0	0	0	0
Research	32	17.7	0	0	0	0	0	0	0	0
Other	35	19.3	6	3.3	1	1.6	0	0	0	0

(n = 181)

Table XV Index of Responsibility

RESPONSIBILITY	CYTOTECHNOLOGISTS		PATHOLOGISTS		SHARED		N/A	
	N	%	N	%	N	%	N	%
Teaching								
Microscopic demonstration	20	10.8	24	12.9	61	32.8	81	43.4
Lectures	14	7.5	35	18.8	57	30.7	80	43.0
Curriculum planning	18	9.7	29	15.6	36	19.4	103	55.4
Research								
Design research protocol	5	2.7	24	12.9	35	18.8	122	65.6
Collect research data	21	11.3	8	4.3	37	19.9	120	64.5
Prepare research manuscript	7	3.8	24	12.9	31	16.7	124	66.6
Policy Development								
Write procedure manual	82	44.1	13	7.0	91	48.9	0	0
Revise procedure manual	69	37.1	14	7.5	102	54.9	1	.5
Devise new procedures	51	27.4	14	7.5	117	62.9	4	2.2
Order major equipment	51	27.4	38	20.4	91	49.0	6	3.2
Develop quality control procedures	45	24.2	24	12.9	116	62.4	1	.5
Prepare budget	42	22.6	41	22.0	77	41.4	26	14.0

(n = 186)

ess, while 26.5% (Table V) of the cytotechnologists said they did it sometimes or always.

Discussion and Summary

Most cytotechnologists (83.8%) reported that they always sign out negative gynecologic specimens with no pathologist's review. This was confirmed by the low percentage (5.8%) of pathologists who reported that negative gynecologic specimens require their review. While just over 30% of the cytotechnologists said they sign out negative nongynecologic specimens, only about 15% of the pathologists indicated that no review was required. However, as noted above, the "sometimes" and "rarely" responses of the cytotechnologists may have had an additive effect. Close to one fifth (18.6%) of the cytotechnologists said that they, at some time, sign out nonnegative gynecologic specimens. This point cannot be compared directly to the pathologists' responses because they had no comparable category on their questionnaire. However, 88.4% of the pathologists said that their review was required for all suspicious or positive cases.

Many cytotechnologists reported that they are expected to know the significance of symptomatology and various modes of treatment (Table II). Pathologists reported that they expect cytotechnologists to screen and mark cell blocks and often, to interpret tissue fragments from aspiration biopsies (Table VIII). More than one half of the pathologists (54.8%) expect from cytotechnologists a diagnosis in descriptive terminology, with a large number (38.4%) also expecting them to categorize into Class I-V (Table IX). These percentages confirm the often repeated contention that cytotechnologists no longer are expected to merely distinguish abnormal from normal. Furthermore, 46.1% of the pathologists (Table XI) felt that a difference in diagnostic opinion with a cytotechnologist necessitated either a consultation or a compromise diagnosis.

And finally, the large number of management functions shared with cytotechnologists as reported by pathologists (Table XV) is evidence of the broadened range of responsibilities that cytotechnologists must assume.

Conclusion

The data reported here describe the practice of cytotechnology in the broadest sense. Cytotechnology practice is described not only in terms of preparation and diagnosis of specimens, but also in terms of responsibilities for general management functions, research, teaching, and the like. This is a baseline study, to be repeated in the future, to measure the changes and shifts of cytotechnologists' responsibilities. These are important data to be used by pathologists, cytotechnologists and perhaps most importantly, by educators who wish to prepare capable cytotechnologists.

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Medical Technology *Essentials*

The National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) has prepared a Preliminary Discussion Document proposing possible revisions of the *Essentials* for an Accredited Program for the Medical Technologist. This document is available for distribution to interested persons for the purpose of providing review and soliciting early input by all concerned. The feedback received in writing and at public meetings held to discuss this document will be used in preparing the draft to be considered by NAACLS and the Committee on Allied Health Education and Accreditation (CAHEA).

Public discussion sessions are planned for April 11, 1983 in Chicago in conjunction with the ASCP/CAP Spring Meeting and for June 14, 1983 in Los Angeles in conjunction with the ASMT Annual Convention. Persons interested in receiving a copy of this Preliminary Discussion Document should send a written request to Carol M Elkins, Executive Director, NAACLS, Suite 608, 547 W Jackson Blvd, Chicago, IL 60606.

Cytotechnology Program Curricula

Ann H. Clark, MAT, CT(ASCP), CMIAC

Historical Perspective

Dr George Papanicolaou presented the first teaching programs in cytology. Persons interested in applying cytologic concepts went to his laboratory and were taught for variable lengths of time ranging from a few days to years. Dr Ruth Graham, among others, became proficient in the application of this method to diagnostic problems and began to train interested persons for varying lengths of time. The educational process continued in this fashion through the late 1940s and 1950s. As the application and utilization of these methods became more widespread, more people were being taught the method at varied sites around the country. In the late 1950s, movement was made toward certification of cytotechnologists and the accreditation of cytotechnology education programs.

Guidelines for curriculum content were lacking, other than those given in the Essentials which were minimal. Programs were diverse, yet primarily emphasized study of the female genital tract, respiratory tract, and body cavity fluids. Specimens from the stomach, urinary bladder, and breast were examined in some centers, but these types of specimens were not universally studied.

In the 1960s, publications began to appear on the cytology of the stomach, endometrium, urinary bladder, and breast secretions. Additional body systems were now being studied, and the curricula were modified accordingly. The Cytotechnologist Manual,[1] first published in 1962, served as the only curriculum guidelines for the programs at this time. The female genital tract, respiratory system and body cavity fluids were emphasized in the manual, while other body systems received cursory treatment. In 1961, Koss[2] published *Diagnostic Cytology*, a text of 380 pages that updated the early publications and gave structure to the subject matter. In 1965, Reagan[3] published his monograph on adenocarcinomas of the cervix and uterus which extended the cytology curriculum into these areas.

In the 1970s, many excellent books were published that covered general subjects such as the microbiology of the vagina and respiratory tract and special subjects such as new collection techniques using brushes for cytologic study of the gastrointestinal tract. Koss[4] published his third edition of *Diagnostic Cytology* in 1979, expanded to 1,266 pages exclusive of a 47-page index. This three-fold increase in pages graphically demonstrates the advances that have occurred. A fourth edition of the Cytotechnology Manual,[5] published in 1975, has rapidly become outdated.

In 1972, an Ad Hoc Committee on Educational Standards for Cytotechnologists of the American Society of Cytology published a Basic Recom-

Table 1: Recommended Basic Curriculum for Cytotechnology

Phase 1		Interphase	Phase 2
General	12 weeks	Cytopreparatory Record Keeping Medical Literature (This phase may occur at any time the throughout the 52-week training period.)	Diagnostic Microscopy (Prescreening of current clinical material) This may be given as a block of 26 weeks following Phase 1, or may be interspersed throughout the curriculum as specific subjects are introduced *Maximum total* 26 weeks
Female Genital Tract			
Respiratory Tract	4 weeks		
Body Cavity Fluids	2 weeks		
Alimentary Canal	1½ weeks		
Urinary Tract	1 week		
Breast Secretions	½ week		
Special Cytology	1 week		
(Flexible)	4 weeks		
Minimum Total	26 weeks		

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mended Curriculum in *The Cytotechnologist Bulletin.* The curriculum guidelines were based on a 12-month, 52-week academic year and recommended 26 weeks of didactic instruction and 26 weeks of clinical practice (Table I). This rough outline served as the curriculum guidelines until 1978 when the Board of Registry published basic knowledge outlines for the certification examinations. These more extensive and detailed outlines now serve unofficially as curriculum guidelines in the absence of other publications in this area.

These documents outline basic science knowledge and specific cytologic applications for the female genital system, respiratory system, the alimentary canal (from oral cavity to colon), body cavity fluids, urinary system, and breast secretions. The American Society of Cytology curriculum guidelines included a block of special subjects interspersed among the subsequent knowledge outlines. Both documents avoid mentioning the interpretative and managerial responsibilities of cytotechnologists because there are varying opinions as to what these responsibilities should be.

Results of Surveys

Recent surveys of cytotechnologists conducted under the auspices of the Cytotechnologist Programs Review Committee (CPRC) of the American Society of Cytology (ASC), in affiliation with the Committee of Allied Health Education and Accreditation (CAHEA) have now defined these areas of previously undocumented technical and managerial responsibilities. These surveys have pointed out deficiencies in the previously defined curriculum as follows:

- 67.5% of cytotechnologists are expected to review histologic slides
- 30.1% sign out negative nongynecologic specimens with no review by a pathologist
- 86.5% implement new cytopreparatory procedures
- 93.1% are responsible for problem solving in relationship to cytopreparation
- 57.6% teach clinicians at some time
- 64.7% teach hospital personnel
- Many are responsible for significant aspects of laboratory management.

Teaching of these skills requires alterations in the classic cytotechnologist curriculum. Students must be taught histologic tissue interpretation in relation to cytologic preparations, problem solving techniques, and basic principles of education and management. In addition to this, the information taught and the skill levels that must be attained in nongynecologic cytology must now be sufficient to allow cytotechnologists to assume the responsibility of reporting evaluations directly to the referring physician.

A separate survey of pathologists has revealed that cytotechnologists also must interpret tissue fragments, examine and evaluate cell block preparations, describe cellular changes utilizing diagnostic terminology, prepare and deliver lectures, and participate in research. This survey also showed that degree-level cytotechnologists (by a margin of 4:1 in the opinion of the employing pathologists) were better able to perform these duties and responsibilities.

New Diagnostic Areas

The development of fine-needle aspiration techniques and the acceptance and application of this skill in the United States will continue to have a marked effect on the curriculum content of cytotechnology programs.

Intrathoracic and intraabdominal needle aspirations bring into the diagnostic realm topics that have not been previously addressed such as benign and inflammatory lesions of the lung and tumors of the mediastinum, pancreas, liver, kidney, and retroperitoneum. Cytotechnologists also must learn more about lymph node, breast, and soft tissue pathology, which also entails significant expansions of the classic cytotechnology curriculum. Content outlines for aspiration cytology will soon be published by the Cytotechnologist Examination Committee of the Board of Registry.

Management, Education, and Research

The field surveys show a need for development of skills in management. Historically, cytotechnologists have not been thought to be involved in laboratory management. Now instruction in basic management techniques must be included in program curriculum (Table II). The skill levels to be attained in educational and research methods are relatively minimal, but certainly students must become knowledgeable in the basic methods in order to perform such on the job duties as contributing to departmental conferences and assisting in research projects. Tables III and IV list education and research items that should be included in cytotechnology curricula.

Table II. Outline of Management Skills to Include in Cytotechnology Curriculum

Laboratory Systems and Procedures
Writing and Development of Manuals, Protocols
Purchasing Procedures
Budget Development
Evaluation of New Equipment
Quality Control Systems
Infection Control Methods
Fire and Safety Procedures
Record Keeping Systems
Personnel Evaluations
Reporting Methods
Computerized Record System
Cost Effectiveness
Inventory Methods
Compilation of Annual Reports and Statistics
Problem Solving Methods

Table III. Outline of Educational Skills to Include in Cytotechnology Curriculum

Preparation of a Teaching Assignment
Development of Program Objectives
Development and Utilization of Visual Aids
Assessment and Evaluation Methods

Table IV. Outline of Research Methods to Include in Cytotechnology Curriculum

Development of a Hypothesis
Development of an Outline
Methods of Scientific Research
Correlation of Results
Performance of a Literature Search
Development of a Bibliography
Construction of Charts and Tables
Writing a Scientific Paper

Student Competencies

If the field studies are used as guidelines for cytotechnologists' duties in the laboratory, students completing a cytotechnology program should possess basic competencies in cytology knowledge and techniques. A summary of these competencies will be found in Table V.

Table V. Summary of Basic Competencies in Cytotechnology Knowledge

1. Upon presentation of a cytologic specimen to the laboratory, the student will be able to:
    - Accept or reject the specimen
    - Select and perform the most advantageous preparation technique
    - Select and perform the most advantageous staining procedure
    - Coverslip and label the specimen
    - Apply the principles of quality control
    - Solve problems in staining and preparation procedures
    - Evaluate and implement new preparation procedures
2. When given cervicovaginal cellular spreads, the student shall be able at the microscope to identify and discriminate:
    - The various normal cellular constituents
    - The various inflammatory cells
    - Microorganisms and their effects on cells
    - Manifestations of cellular degeneration
    - Benign atypias
    - Dysplasia, by degree and morphologic origin
    - Carcinoma-in-situ
    - Microinvasive carcinoma by morphologic type
    - Invasive squamous cell carcinoma by morphologic type
    - Cellular effects of radiation and chemotherapy
    - Post-irradiation dysplasia
    - Adenocarcinoma of endocervix and endometrium and their precursors
    - Extra-uterine malignancies
    - Rare uterine tumors
3. The student upon completion of the program shall be able to evaluate gynecologic material with sufficient competency to meet the job entry-level responsibility of issuing the final report for negative gynecologic specimens.
4. When given cellular samples from the respiratory system, alimentary tract, genitourinary system, breast, body cavities, including cerebrospinal fluids; and from transthoracic, transabdominal, and surface nodule fine-needle aspiration, the student shall be able to identify microscopically and discriminate:
    - Normal cellular constituents
    - Inflammatory cells
    - Microbiologic entities and associated cytomorphology
    - Manifestation of cellular degeneration
    - Benign atypias
    - Cellular manifestations of various premalignant processes
    - Squamous cell carcinoma, adenocarcinoma, and other malignancies
    - Cellular effects of radiation and chemotherapy
    - Altered cellular morphology due to data collection methods
5. When given a cellular preparation, the student shall detect, select, and clearly mark the cells most representative of any pathologic process present. (The detector skill is the primary skill to be attained. Competency in cellular detection at a high level of accuracy is essential in all types of preparations.)
6. Upon detection of cellular manifestations of disease, the student will develop a differential diagnosis supported by cellular evidence and pertinent cognitive knowledge in conjunction with clinical history and data. A report shall be prepared for the pathologist incorporating all these facets of information.
7. The student shall exercise knowledge of symptomatology in the evaluation of cellular morphology and in the development of the differential diagnosis.
8. The student shall possess cognitive knowledge of treatment modalities to be utilized in the evaluation of cellular morphology and the development of the differential diagnosis.
9. The student shall be able to evaluate cellular morphology in cell block preparations.
10. The student shall have cognitive knowledge of and be able to utilize diagnostic terminology in reporting to the clinician or the pathologist.
11. The student shall be able to review histologic tissue sections for the purpose of quality control and to build cognitive correlation between tissue patterns of disease and cellular manifestations of disease.
12. The student shall be able to read and evaluate published professional literature, evaluate its pertinence and reliability, and to utilize such material in the preparation and evaluation of specimens.

(Continued on next page)

Program Impact

As the curricula are expanded to teach the skills and competencies deemed necessary by the field studies conducted by the Cytotechnology Programs Review Committee, the contact hours for the students have not been expanded in most programs. Extending programs to 15 months has been advocated; however, university programs have actually decreased the contact time from the customary 48 to 50 weeks to 40 to 44 weeks. Thus, many programs are caught in the dilemma where more must be taught without additional time to teach. It may be educationally sound to utilize prerequisite studies as a method of having some of the teaching occur outside of the allotted program time.

It is customary to have students exposed to basic sciences prior to entrance into a technical program, or to include such information within programs. In general, if students are not adequately prepared to begin a given technical curriculum, then time must be spent within the program to establish these skills. Historically, this has been the situation in cytotechnology programs. But with the expansion of program content to meet current professional needs, cytotechnology programs cannot afford the luxury of utilizing program time in this manner. At the same time, the expanded curriculum demands a more diversified and higher level of basic science knowledge in order to meet the needs of the technical curriculum content.

Prerequisites

Historically, 12 or 14 semester hours of biologic sciences have been the prerequisites for entrance into a cytotechnology program. This has not been advantageous. For example, freshmen biology is a requirement in most undergraduate colleges. The freshman biology course generally comprises a semester of zoology and frequently a semester of botany, neither of which are specifically designed to prepare a student for the cytotechnology curriculum. Yet, these

(Table V continued)

13. The student shall be able to understand the practical components of laboratory organization and management. The student shall be introduced to:
    - Supply inventory methods
    - Annual reports and statistics
    - Budget preparation
    - Reporting methods
    - Policies and procedures manuals
    - Problem solving
14. The student shall be able to incorporate quality control measures in the preparation and microscopic evaluation of submitted specimens as required by various accrediting agencies.
15. The student shall be familiar with and practice laboratory safety measures and regulations.
16. The student shall be able to understand and utilize the principles of educational instruction for the purpose of preparing future continuing education sessions (such as journal club or literature seminar or investigation projects). The student shall be able to:
    - Develop objectives
    - Utilize visual aids
    - Assess the educational experience
17. The student shall be able to understand and utilize the principles of scientific research; the student shall be able to:
    - Develop a hypothesis
    - Outline an experiment to prove a hypothesis
    - Perform the experiment
    - Report, discuss, and draw conclusions from the results of the experiment
    - Perform a literature search
    - Develop a bibliography
18. The student shall have specific knowledge of the ethical role and responsibilities of the cytotechnologist. The student shall be able to:
    - Practice discretion and confidentiality in regards to laboratory and patient reports.
    - Relate specimen evaluation to the significance and impact of such evaluations on patient care
    - Practice honesty and integrity in daily duties
    - Practice the principles of good interpersonal relationships with peers, staff, and faculty

two semesters account for eight of the formerly 12 and now 14 semester hours that are the established prerequisite in the biologic sciences.

To support the cytotechnology curriculum, as documented in the Board of Registry outlines of basic knowledge, courses in histology, cell biology, embryology, anatomy, microbiology, physiology, and genetics are the most desirable prerequisite courses to adequately prepare students for the technical cytotechnology curriculum. Yet previous undergraduate prerequisites after freshman biology required only four and now six more hours in order to prepare for the technical curriculum. In many cases, this basic science information had to be incorporated into the technical year, to the detriment of the technical competencies. Time used to teach basic sciences cannot be utilized for specific technical instruction or clinical practice.

These field studies support the recommendation that the biology prerequisites be increased to a more appropriate level to better prepare the applicants for the technical curriculum. No less than 20 semester hours of biologic sciences appears to be an appropriate requirement for entrance. This would allow eight semester hours in freshman biology and 12 semester hours for preparatory courses in histology, cell biology, embryology, anatomy, microbiology, physiology, and genetics.

Chemistry Prerequisites

Historically, the lack of chemistry prerequisites for cytotechnology has been a serious deficiency in the current accreditation standards. Cytotechnology students and future cytotechnologists must use hazardous and caustic chemicals to prepare stains and reagents. They should at least possess a rudimentary knowledge of chemistry so that they can weigh and mix chemicals, calculate and measure molar solutions, and learn how substances interact, if only to protect themselves. These skills are more advantageously gained in basic college chemistry courses rather than in the cytopathology laboratory.

Summary

This discussion has presented cytotechnology in the 1950s and early 1960s when only three types of specimens were commonly handled, expanding to encompass most body systems with the 1970s. With the present utilization of fine-needle aspiration techniques, all types of pathologic lesions are accessible to the cytologic method. The recent surveys have detected responsibilities not covered in the classic cytotechnology curriculum which must be added in the future. In the next few years, cytotechnology curricula must be greatly altered to fulfill the needs of the profession. To meet future practice needs, cytotechnologists must be taught more in the same time span allotted 20+ years ago. Prospective students in cytotechnology must be better prepared in the biologic sciences before beginning the technical curriculum. This knowledge must be obtained either at the expense of the development of entry level job skills or must be obtained prior to entrance in the program. Prerequisites must also be expanded in the biologic sciences and basic chemistry courses must be included.

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Symposium

Cytotechnology: Current Status of Certification and Program Accreditation

Irma Fortune Rube, MS, SCT(ASCP)

Although performed separately by different organizations, cytotechnologist certification and program accreditation are, and should be, closely interwoven. They relate so closely that any change in one area is soon reflected in the other. Nor does one precede the other; it becomes a cycle. Good certification examination produces cytotechnologists that in time serve well as program faculty. Improved *Essentials* for accredited programs provide better-qualified students, who in turn will be certified and will perform better as cytotechnologists. Both work together toward the common goal of quality assurance for cytotechnology.

Certification

Before the August, 1982 cytotechnology certification examination was administered, 7,764 cytotechnologists were certified by the Board of Registry of the American Society of Clinical Pathologists.[1] Including the 205 examinees who successfully sat for the August, 1982 examination, the total number of certified cytotechnologists rose to 7,969 (personal communication, Board of Registry staff, Oct 1982). While this group may seem small, it is not generally recognized that cytotechnology is the fifth largest of the 16 categories of certification offered by the Board of Registry. Medical technologists are the largest group, followed by medical laboratory technicians, clinical laboratory assistants, and (with slightly more than 11,000 certified) histotechnologists.

The first certification examination in cytotechnology was given in 1957. The 63 persons who successfully sat for it included a five to ten-year backlog of individuals who had trained prior to this time, as well as students just completing training. As can be seen in Fig 1, almost five times as many cytotechnologists were certified from 1961 to 1965 than between 1957 and 1960. The numbers increased until they reached a peak of 2,550 between 1971 and 1975. During 1980 to 1982, 319, 296, and 280 were certified, respectively, a modest decrease from the annual average of 343 for the preceding five years.

As is shown in Fig 2, concomitant observations can be made concerning numbers of cytotechnologists with baccalaureate degrees (unpublished data, Board of Registry staff, 1981–1982). Between 1957 and 1960, more than half of all cytotechnologists had baccalaureate degrees. After the *Essentials* (minimal educational requirements) were adopted in 1962, only two years of college were required for students entering accredited cytotechnology programs. The percentage of students with baccalaureate degrees started dropping and leveled off at 29% at the time when the largest numbers of cytotechnologists were being certified (1971 to 1975). Between 1976 and 1980, an interesting phenomenon occurred. The percentage of cytotechnologists with baccalaureate degrees increased to almost half (48%) *without any change* in the total number of prerequisite academic credit hours required in the *Essentials*. In 1980, 60% or 190 of 319 of the cytotechnologists who passed the certification committee examination had baccalaureate degrees. In 1981 the percentage with baccalaureate degrees dipped to 54%, but increased in 1982 to 63%. This is not the time or place to speculate on why this has happened, debate its significance, or consider potential ramifications. Of further interest is that at the time of certification 3% of cytotechnologists have advanced degrees (2% masters, 1% doctorate). This does not include those who obtained advanced degrees after certification.

Examination Committee

The Board of Registry's Cytotechnology Certification Examination Committee is composed of three cytopathologists and three cytotechnologists. The chairman is elected

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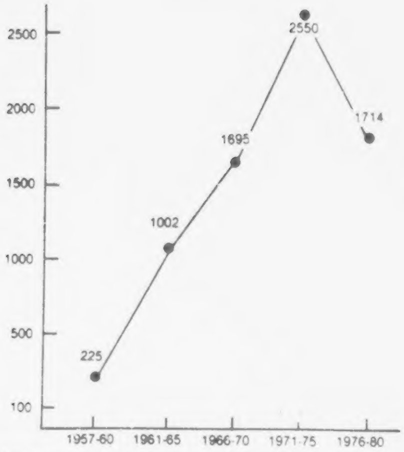

Fig. 1. Number of cytotechnologists certified, 1957-1980.

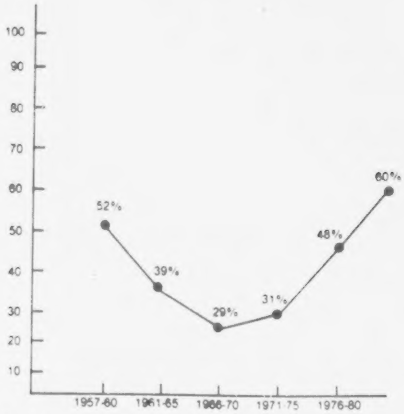

Fig. 2. Number of cytotechnologists with a baccalaureate degree, 1957-1980.

annually from the committee membership and has been a cytotechnologist for the past decade or so. Geographic representation is an important factor in nomination of members and consultants for approval by the Board of Governors. The 1982 roster had members from California, Wisconsin, New York, Pennsylvania, Kansas, and Tennessee, and included consultants from Texas, Maryland, and Illinois.

For the past several years, the committee has been involved in a concerted effort to develop an examination that more closely measures what a cytotechnologist *does* in the laboratory. Included in this effort has been the process of moving from a norm-referenced examination, in which comparisons of peer groups are made, to a criterion-referenced, or competency-based examination. One step in this direction was taken in the August 1982 examination, in which the number of color-plate or visual questions was increased to balance the number of nonvisual or written questions. Another step has been the preparation of a Cytology Laboratory Procedures Questionnaire, mailed in August 1982 to a large number of laboratories. This was an attempt to measure not only *what* a cytotechnologist does, but also the *frequency* with which it is done. Preliminary data from the first 100 replies indicate that the survey is accomplishing its purpose. This information can guide the committee in the future not only on what subject matter to use for questions but also on how much weight (how many questions) to give each sub-category within the examination, eg, female reproductive system, alimentary tract, cytopreparation, etc.

Two developments at the fall 1982 committee meeting indirectly relate to the foregoing discussion. Production of color plates for visual testing made projection of photographic transparencies during examination sessions unnecessary. Examinees could work at their own speed, returning at will to review answers. Thus, even though the visual portion of the examination has been lengthened, total time for completing the examination has diminished. Carefully obtained time studies repeated during numerous examination cycles has led the committee to recommend that the examination be given in one five-hour session, a format used for most other certification examinations.

Again keeping in mind the present written-visual balance of the examination and making comparison studies in scoring methods over several cycles, the committee recommended that beginning in February 1983, one pass-fail standard be used for scoring. The examination will continue to have two major divisions: written and visual. Reports to examinees and programs will be analyzed on this basis and will include a list describing the general content and taxonomic level of each question. The examinee will no longer be required to achieve two separate minimal pass scores. The written and visual components will be graded as one examination.

Another step in the development of a competency-based examination has been the publication of a knowledge outline for aspiration cytology. Allowing ample time for assimilation into the curricula of cytotechnology training programs, questions on this important new aspect of cytopathology will gradually be introduced in future examinations.

Program Accreditation

The first minimal educational standards or *Essentials* for accredited programs of cytotechnology training were adopted by the House of Delegates of the American Medical Association in 1962. They had been developed by the Cytology Committee of the American Society of Clinical Pathologists and the Board of Schools. In 1975 the American Society of Cytology formed the Cytotechnology Programs Review Committee (CPRC) in collaboration with the AMA Council on Medical Education and assumed the responsibility undertaken only the year before by the newly formed National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). Since that time, the Cytotechnology Programs Review Committee has handled self-study evaluations, reviews, and site visits for new programs and for reevaluation of established programs. While CPRC evaluates and recommends, CAHEA grants accreditation. These relationships and procedures are explained in detail in the *Allied Health Education Directory*.[1]

As is shown in Fig 3, there were 77 cytotechnology programs accredited in 1963. The number of accredited programs reached a peak of 118 in 1970 and 1971, coinciding with the time interval for the greatest number of certified cytotechnologists. From 1972 to the present there has been a steady decline in the number of accredited programs. The greatest drop (96 to 75) occurred between 1978 and 1979, one year after revision of the *Essentials*.

As of November 1982, there were 66 CAHEA-accredited cytotechnology programs plus one new approved program pending accreditation (personal communication, Cytotechnology Programs Review Committee, Nov 1982). Three of the 66 programs were inactive. California and Texas each had five programs, while Ohio and New York had four each. Fifteen states had no cytotechnology program.

Twenty-seven of 66 (41%) of the accredited programs are qualified to confer a baccalaureate degree on completion of training. Twelve of these have options of certificates or degrees for students; the remaining 15 confer only degrees. The new program pending accreditation is a baccalaureate degree program.

Seven programs have ceased since November 1981, five of which had student capacities of only four. It would appear that the smaller programs are finding it more difficult to remain in operation; however, 27 of the active accredited programs have only a four-student capacity. Fourteen programs have a student capacity of ten or more.

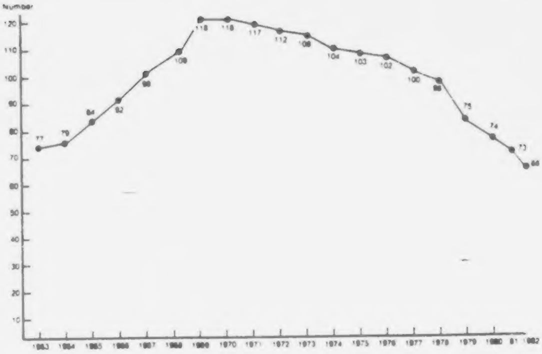

Fig 3. Number of CAHEA-accredited programs in cytotechnology. (Modified from Allied Health Education Directory.[1])

Programs Review Committee

The Cytotechnology Programs Review Committee is composed of eight members, four pathologists and four cytotechnologists. The committee chairman is appointed by the president of the American Society of Cytology and historically has been a pathologist.

The routine work of the committee is of considerable magnitude and has been briefly outlined above. Another assignment of this committee is the periodic review of the *Essentials* with guidelines for accredited programs, an activity in progress for several years. The work is nearing completion and announcements should be forthcoming in the near future.

Conclusion

The foregoing discussion demonstrates with certainty that certification and accreditation of cytotechnologists are dynamic processes that are in a constant state of evolution.

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Symposium

Where Are The Applicants?

Marion Holmquist, CT(ASCP), CFIAC

The number of applicants for the cytotechnology program at the Louisiana State University Medical Center has shown a downward turn so marked that no degrees in cytotechnology were awarded in 1981. In order to determine if the problem in Louisiana is unique, a short questionnaire was sent to other cytotechnology programs asking about their experience in recruiting. The response was gratifying (Table I); many took time to write thoughtful and incisive letters on reasons for the shrinking applicant pool.

In 1980, eighty-one approved and accredited programs were in operation in the United States and Puerto Rico (Table II); 66 were active, 15 inactive. Following the 1970 decision by the Department of Health, Education, and Welfare (HEW) to eliminate the Cancer Control Program that provided grants to schools and stipends to students, the number of cytology schools dropped from 118 to 100 and enrollment fell from 511 to 325 students (36% decline).[1,2] This downward trend has continued and was further accelerated when Medicare regulations banned the use of patient-derived funds for education. The number of degree programs has increased, however, primarily because of the formation of schools of allied health in several universities. In 1980, there were 45 certificate programs and 21 degree programs, of which only two thirds were filled.[3]

Information from a study conducted by the Cytotechnology Program Review Committee (CPRC) of the American Society of Cytotechnology (ASC) indicates that 60% to 70% of entry level cytotechnologists have degrees, the majority of which were obtained prior to the program. Clearly, the trend is toward fewer graduates (Figure) who have more education. The number of certificates-only graduates is also declining. If the number of cytotechnologists entering the field is growing smaller, what impact will this have on the work force and will more be needed? Attempts to answer these questions must be based on estimates and projections because hard statistics for cytotechnology are lacking.

Table I: Programs Responding to Questionnaire

Total — 50 (62%)
Active — 39 (59%)
Inactive — 11 (73%)
Certificate — 22 (49%)
Degree — 17 (81%)

In 1977, Ng documented the current status of practice and training in cytology.[4] He sent a questionnaire to 1,500 pathologists selected from the mailing list of the American Society of Clinical Pathologists. Responses were received from pathologists in 704 laboratories that provided anatomic pathology service, 675 of which also provided cytology services (96%). Of these laboratories, 21.8% did not employ cytotechnologists.

The survey information provided by Ng indicates that there are an estimated 6,000 pathology laboratories in the United States that provide cytology services and examine approximately 100 million cytologic samples annually. Almost all laboratories (97.2%) processed both gynecologic and nongynecologic samples in a mean ratio of approximately 12:1 (92% to 8%).

The workload for cytotechnologists recommended by the ASC is 12,000 cases per year for gynecologic and 3,000 cases per year for nongynecologic samples. Thus, it would require 10,334 cytotechnologists to perform the 100 million examinations annually; or, if an additional 20% are needed to perform laboratory tasks other than microscopic examinations, approximately 12,400 cytotechnologists may be needed.

The Board of Registry certified 7,689 cytotechnologists from 1957 to 1981 (B. Castleberry, personal communication, Oct 1981). In 1980, 4,517 paid the annual registration fee; of these, however, the actual number who are practicing cannot be determined. A 1979 study by ASC revealed that the number of certified cytotechnologists currently at work is 3,500.[5] If these

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From the School of Allied Health Professions, Louisiana State University Medical Center, New Orleans, LA 70112

Table II: Status of Programs as of October, 1980

81 Approved and Accredited Programs
in United States and Puerto Rico
66 Active Programs
58 Certificate
23 Degree
15 Inactive Programs
13 Certificate
2 Degree

Table III: Questionnaire to Directors of Cytotechnology Programs

1. Do you usually fill your quota?
2. Ratio of applicants to accepted students.
3. Caliber of students.
4. Does the job market (availability of jobs, salary) affect recruitment?
5. Comments on recruitment.

estimates are correct, there clearly is an overall shortage.

Survey Results

The format of the 1980 questionnaire circulated to the 81 cytotechnology programs is shown in Table III. Responses were received from 50 of the 81 programs (62%). Following are tabulations of the responses and a summary of individual comments.

1. *Do you usually fill your quota?*

	Yes	No
Certificate	50%	50%
Degree	41%	59%
Both	46%	54%

Comments received from the degree programs not filling their quotas blame high tuition costs for the small number of applicants, and virtually every qualified applicant is accepted to most programs. Comments from the unfilled degree programs also indicate that there is great difficulty in recruiting students to their programs. Some blame is cast on admissions offices where there is a basic lack of understanding of who and what cytotechnologists are, making recruitment less than effective. Potential students are more apt to be directed to the better known professions of nursing, dental hygiene, radiologic technology, or medical technology, with some stigma that cytopathology is a second-class program.

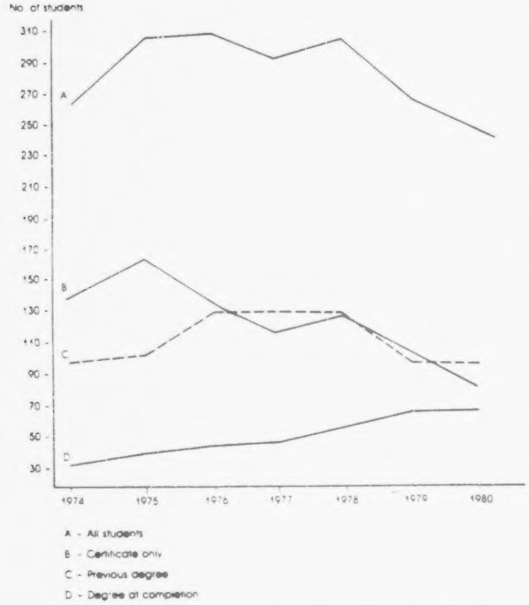

Figure Distribution of Students Graduating From Cytotechnology Programs 1974–1980

2. *What is the ratio of applicants to accepted students?*

	Average	Range
Certificate	2.3:1	1–6
Degree	1.6:1	1–6
Both	1.8:1	1–6

The comments reveal that the ratio continues to decline and most programs indicate that the number of qualified applicants is either equal to or less than quotas in most programs and that little choice among qualified applicants is available to program directors.

3. *How do you rate the caliber of students?*

	Increasing	Decreasing	Stable
Certificate	50%	18%	27%
Degree	47%	12%	35%
Both	49%	15%	31%

The responses and comments indicate some ambiguity of this question; however, there is general consensus from both the degree and certificate programs that the caliber of most students is higher. This is to some extent tied to the increasing percentage of applicants who have completed baccalaureate programs and reflects higher scores on the registry examinations. Contrarily, some programs are forced to accept students with lower grade point averages or minimal credentials in order to meet quotas. One respondent expressed the opinion, however, that the GPA is not necessarily tied to motivation and success. Experience among some has shown that students with an overall "C" average often are better motivated and do better in their clinical year than those with higher averages.

4. *Does the job market (availability of jobs and salary) affect recruitment?*

	Yes (neg)	Yes (pos)	No
Certificate	45%	—	41%
Degree	41%	25%	35%
Both	44%	10%	38%

The general consensus is that the salary scale for cytotechnologists is low which has an adverse effect on recruitment. Despite the overall need for cytotechnologists, job availability in some areas is minimal. It is perceived that recruiters find it easier to "sell" a program if jobs are plentiful and salaries are improving, which is not always the case with cytotechnology. Comments from one of the higher paying institutions indicate that cytotechnologists are paid a starting annual salary of $14,000, reaching $20,000 after nine years' experience. This represents about a $5,000 lower differential from medical technologists, a difference to some extent related to the mandatory degree required of medical technologists, placing them in a generally higher pay scale. Job security was listed as a positive factor in recruiting.

Question 5 asked for further comments on recruitment. Following is a sampling of the replies received.

Comments from Certificate Programs

- Recruitment problems are mainly a result of a dearth of recruitment materials, the lack of knowledge of the field by vocational counselors, and a generally low profile that needs a strong promotional campaign on a national level.
- Pathology, including cytopathology, has a limited image even with medical peer groups, but particularly with the general public. The need for public relations/information work to define and enhance information regarding pathology-related fields is obvious. What's being done about it on a national and state level?
- College students, professors, and guidance counselors need to be made aware of cytotechnology as a potential career field, the nature of the work, and the type of training required.
- The major task in the recruitment process is informing the public that our school exists.
- I see lack of visibility and public awareness of the field to be a major problem in recruitment. If an individual has not even heard of the profession, he certainly cannot consider it as a career possibility.
- I do not think certificate programs are attractive to interested, motivated, undergraduate students who are well qualified but do not wish to enter a program offering no academic credit. Another deterrent is the ignorance and lack of publicity about cytology in general and what it involves. A current, professionally made film emphasizing the wide range of cytology in the diagnosis of diseases other than cervical cancer and the skill and training involved would be of great help.
- We have an identity problem—people do not know who we are or what we do—we need a campaign for public awareness.

Comments from Degree Programs

- Because we are a degree program in a state university, many students who inquire from out-of-state never apply, primarily because of the increased tuition.
- Recruitment in the allied health professions is low due to two major factors: (1) investment return on the expense of education (salaries) and (2) job field popularity.
- One must consider the respect of the job by other peers in health care delivery and the job status to have a full understanding of job satisfaction for cytotechnologists. The sensationalism surrounding the ASC's report on the Papanicolaou smear, no matter how inaccurately interpreted, does have some effect on those in the field and those considering it.

There are other reasons for the decrease in applicants to cytotechnology programs, as follows:

Declining birthrate. From 1961 to 1973 the annual number of births declined from 4.3 to 3.1 million.[8] As the low birth groups reach traditional college age (18–24), many colleges will be faced with declining enrollments. The number of applicants in February, 1982 decreased in 53.9% of colleges and universities compared to the number in February 1981.[7] This will become precipitous after 1985.[8]

Job market. This has opened up to women now. In 1979, for the first time since World War II, more women than men were enrolled in American colleges. The number of women entering the nation's 126 medical schools more than tripled during the 1970s. According to the US Census Bureau, women comprise 41% of the work force. Work knows no gender now: a woman can drive a 16-wheeler, be an airplane pilot, or enroll in the Military Academy at West Point. According to one study, the 15 most promising careers for a woman are accounting, banking, clerical, computer, construction, engineering, engineering-science technology, health services, insurance, law, law enforcement, management and administration, sales, services, and stockbroker.[9]

Salaries. In 1910, women were paid an average of 55¢ for each dollar earned by men for the same job. Today it is 59¢.[10] In South Carolina 87% of jobs paying $25,000 or more are held by men. Now that there are laws banning wage discrimination, women are increasingly turning away from low-paying traditionally female occupations. The average salary offer for a bachelor's degree in 1978–79 is listed in Table IV.

Table IV. Average Salary Offer for Bachelor's Degree — 1978–79

Business	$14,484
Engineering	17,968
Humanities	11,484
Sciences	
Biological	11,700
Chemistry	15,828
Computer science	16,572
Health professions	13,248
Mathematics	15,848

As is shown, the salary for the health professions is below most of the others listed. The salary for a cytotechnologist is reported to be $10,000–$12,000 without a degree and $11,000–$16,000 with a bachelor's degree.[11] The curriculum is difficult in the preclinical years and many required courses are the same as those for medical and dental school. Once the student learns that the earning power of most of the allied health professions is far less than other fields of study, the student either switches to one of the higher paid professions or a shorter and less demanding course of study.

Also, it is not only the starting salary that dissuades prospective applicants, but the future potential. In order to attract good people who will take responsibility for decision-making in a diagnostic field, the compensation at the end of the ten years should at least double the entry level salary and continue to rise if the person is capable.

Recruitment

The shrinking pool of applicants is a problem for all the health professions, and there is a scramble to enlist the few available. The students with the highest grade point averages are wooed into other fields with higher salaries and more professional recognition. But one of the most damaging aspects of recruitment is the lack of awareness of the profession, both by the public and particularly by the guidance counselors who direct the future of the students. A student who contemplates cytotechnology as a course of study may make another choice when his family, friends, and counselor ask, "What is that?"

One successful program is conducted at the Thomas Jefferson University by Dr Lawrence Abrams, Dean, College of Allied Health Sciences.[12] Dean Abrams has devised a highly successful mechanism for interesting and involving high school students in health careers. In 12 years of existence, his Guidance Clinics have been consistently over-subscribed. A by-product of the Health Careers Guidance Clinic is a Guidance Manual providing comprehensive health career guidance information for the Greater Philadelphia Region. The manual contains in-depth sections on health careers, job descriptions, and brief summaries of health careers aimed at the high school student. It is an excellent program.

In the Letters to the Editor section of the August, 1981 issue of *Cosmopolitan* magazine, there are three letters in response to a previous article spotlighting the nursing profession. One comment states that the article was the first *honest* article about the nursing profession. How many articles have appeared lately in general reading material on the cytotechnology profession, honest or otherwise? There have been a few in scientific journals only. The public needs to know about cytotechnology. Cytotechnologists must come out of the closet by writing articles, letters to the editor, and speaking before groups. The profession of cytotechnology must be publicized because it is from the public that our future applicants will come.

Job Dissatisfaction

In a national survey conducted in 1978 by *Psychology Today* magazine, 23,008 readers answered questions on "How Do You Like Your Job?"[13] Most who answered were generally satisfied with their jobs for now, but there was an undercurrent of restlessness that, according to the authors, may create problems for employers in the 1980s. What the readers wanted was not simply more money and benefits, but more psychologic satisfaction, opportunities to learn and grow, chances to exercise their talents and skills to the fullest, and greater possibilities to accomplish something worthwhile. The report goes on to say that the participants in the survey wanted more control over decisions in the workplace, especially those that affect their own jobs and more freedom to set the pace of their own work. Workers have a whole hierarchy of needs that they see as necessary, what Abraham Maslow called self-actualization. The emphasis on personal growth has been noted before. What is different about this generation is that if they do not get what they want, they may leave. No less than two thirds of those who answered the survey reported that there was some likelihood they would change occupations within the next few years.

The profile of participants that emerges from this survey is based on the highest percent answering in each category: full-time wage and salaried professional women, age 25–34, married, salary range \$10,000–\$14,999, graduate or professional degree (some college a close second). Does this sound like the description of someone you know?

In "A Profile of Cytotechnologists,"[14] the results of a questionnaire sent to 78 students graduated with a bachelor of science degree in cytotechnology from the Medical University of South Carolina since 1972 are reported. The profile that emerges is somewhat contradictory:

(1) There was a high tendency for graduates to work in their profession.

(2) Three fourths of them are members of a professional society (the highest of ten allied health professions surveyed).

(3) Almost one half are dissatisfied or neutral with their professional role, and 60% would not choose the profession again or are undecided.

These contradictions, according to the authors, may explain why there is a tendency for cytotechnologists to seek a graduate degree or other education that may change their professional role.

An article in the August, 1982 LABORATORY MEDICINE asked "Why are Medical Technologists Dissatisfied?"[15] The conclusion states that the theories of Maslow seem to hold true for medical technologists; that is, the most important rewards are those that come from a service of personal worth and realization of a job well done. The most dissatisfied members of the group surveyed had been in the profession more than seven years and had unrealistic job expectations that were not being met.

Another study on factors contributing to attrition in medical technology appeared in same issue of LABORATORY MEDICINE.[16] The results of this study suggest that the education received by the medical technologists prepares them to do and be much more than their present role in the laboratory allows. Almost all factors listed in the survey that potentially influenced professional attrition relate to the need for self-actualization; they indicate that deficiency of this satisfaction is most influential on professional attrition. Is this frustration affecting cytotechnologists as well?

According to Elmer Koneman, MD,[17] expressions of job dissatisfaction apparently have not gone unnoticed by undergraduate students and their counselors. He states that if this trend continues, laboratories in the near future face the prospect of being staffed by individuals with less experience and lower aptitudes, potentially jeopardizing the high quality of service that presently characterizes laboratory practice.

Heading the list of potential job satisfiers that were listed by Myers and associates[15] is "Trust of Pathologist Director." One application of this, unique to the field of cytopathology, is trust in the adequate training and subsequent knowledge in the field of diagnostic cytology. According to a survey done by Ng in 1977, 43% of pathologists had no exposure to cytology at all during their residency and less than 20% appeared to have adequate formal training.[4]

Along these same lines, Patten states, "The average pathologist with responsibility for cytodiagnosis often has not received adequate initial or continuing education in the field of diagnostic cytopathology. This statement is documented by recent studies from an annual cytopathology laboratory testing program in New York State. On initial examination approximately 15% of pathologists having to screen and interpret cytologic specimens without the aid of cytotechnologists did not meet minimum standards."[18]

Acknowledging a need to elevate standards in cytopathology, the American Society of Cytology recommended that certification in anatomic pathology should be awarded only to those who can pass a thoroughly adequate examination in cytopathology.[5]

In contrast, cytotechnologists have been trained in programs that are surveyed, accredited, and reviewed periodically to assure high standards and certified by means of a national examination. In short, many cytotechnologists are better trained than pathologists. This is an unhealthy situation. The inability to be challenged and mentally stimulated by one's employer is a strong factor in job dissatisfaction.

The ASC sets standards for certifying a cytopathology laboratory director as a qualified cytopathologist in its Laboratory Accreditation criteria. Only about 40 laboratories have requested this voluntary acreditation. One of the essentials in this program is a minimum of 10,000 cases annually to be eligible. Since nearly one half (48.8%) of the cytopathology laboratories process fewer than 10,000 cases a year, it would seem advantageous to eliminate this minimum requirement and not disfranchise half the laboratories processing cytopathology from ASC approval. It would stimulate more laboratory directors to become members of ASC.

Raising The Essentials

Another letter in the August, 1981 *Cosmopolitan* was written to correct the author's definition of "physician associates." It states, "We (physician associates) are distinguished from other medical personnel by our ability to intergrate and interpret findings on the basis of general medical knowledge and to exercise a degree of independent judgment."

This could be a definition for cytotechnologists as well. Cytotechnologists are qualified to report negative cytologic findings. This certainly requires a degree of independent judgment and it is based on integrating and interpreting findings on the basis of general medical knowledge. Also, if this characteristic is a measurement of upper level professionals, then how is it that cytotechnology has some of the least demanding requirements for admission of all the allied health professions? How can future applicants be convinced that cytotechnology is a challenging field, requiring a mature, dedicated individual, upon whom a pathologist relies heavily to select a relatively few abnormal cells from millions of normal ones so as to accurately diagnose a malignancy? Should this individual have less of a science background and be less of a mature individual than other health professionals?

In an excellent article on the impact of the allied health professions in health care, McTernan[19] lists 40 different occupational groups contributing to health care, emphasizing there is still much to be done in convincing physicians, other health professionals, and the public at large that they are health professionals in their own right. Cytotechnology is not even on the list of occupations recognized as an allied health profession! If the other 40 groups are having trouble with identity, can you imagine the job cytotechnology has!

It is shortsighted to say that a higher salary is the main reason for wanting to raise the essentials to a bachelor of science degree for the field of cytotechnology. Lack of adequate compensation is one result of the problem, but many of the best applicants are selecting other fields of study when they learn that cytotechnology is not a national degree program and does not enjoy as much professional recognition as other fields of study.

Conclusion

The question of "Where Are The Applicants?" has many answers. Some of the problems such as declining birthrate and subsequent college enrollment and an increased job market for women are impossible to alter. But there are other factors that can be addressed, such as enhancing the image of cytotechnology, both with the public and peers; addressing issues of job dissatisfaction; increasing salaries to an acceptable level; raising the essentials for training programs; and increasing recruitment, particularly at the high school level. These are issues that can be addressed by the profession. Indeed, they must be addressed to ensure the future of cytotechnology.

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Essentials and Guidelines of an Accredited Educational Program for the Cytotechnologist

Essentials initially adopted 1962; revised 1967, 1977, 1983

Adopted by the

AMERICAN MEDICAL ASSOCIATION
AMERICAN SOCIETY OF CYTOLOGY

Program Review Committee

CYTOTECHNOLOGY PROGRAMS REVIEW COMMITTEE

> *Essentials*, which present the minimum accreditation standards for an educational program, are printed in regular typeface in outline form. The extent to which a program complies with these standards determines its accreditation status, the *Essentials* therefore include all requirements for which an accredited program is held accountable.
>
> Guidelines, explanatory documents which clarify the *Essentials*, are printed in italic typeface in narrative form with numbered lists. Guidelines provide examples and clarification to assist in interpreting the *Essentials*.

PREAMBLE

OBJECTIVE

The American Medical Association and the American Society of Cytology cooperate to establish, maintain and promote appropriate standards of quality for educational programs in cytotechnology and to provide recognition for educational programs which meet or exceed the minimum standards outlined in these *Essentials*.

These standards are to be used for the development and self-evaluation of cytotechnology programs. Site-visit teams assist in the evaluation of program compliance with the *Essentials*. Lists of accredited programs are published for the information of prospective students, employers, and the public.

The Cytotechnology Programs Review Committee of the American Society of Cytology reviews programs applying for accreditation by the Committee on Allied Health Education and Accreditation (CAHEA) and makes recommendations for accreditation or non-accreditation to CAHEA. CAHEA, in turn, acts on these recommendations.

Cytotechnologists are educated in these accredited programs to work under the direction of qualified physicians.

DESCRIPTION OF THE PROFESSION

The professional roles of cytotechnologists include cytotechnologists at entry level, cytotechnologists with experience of a variable number of years who function under limited supervision and serve as senior cytotechnologists, cytotechnologist laboratory managers, cytotechnologist-educators and those involved in research.

Competencies required of cytotechnologists have been based on field studies of on-the-job cytotechnologists. These studies were conducted by the Cytotechnology Programs Review Committee of the American Society of Cytology and were designed to reflect the skills required by the entry level cytotechnologist.

The primary objective of cytologic education is to prepare individuals to perform the following functions with competence.

1. Upon presentation of a cytologic specimen to the laboratory, the cytotechnologist will be able to:

   Accept or reject the specimen
   Select and perform the most advantageous preparation technique
   Select and perform the most advantageous staining procedure
   Coverslip and label the specimen
   Apply principles of quality control
   Solve problems in staining and preparation procedures
   Evaluate and implement new preparation procedures

2. When given cervicovaginal cellular samples, the cytotechnologist will be able to use the microscope to identify and discriminate among the following entities:

   The various normal cellular constituents
   The various inflammatory cells
   Microorganisms and their effects on cells
   Manifestations of cellular degeneration

B. Accredited educational programs may be established in colleges and universities, hospitals and clinics, laboratories, medical schools, postsecondary vocational/technical schools and institutions, and other acceptable institutions which meet comparable standards for education in this field.

Programs may be locat[illegible] one or more of such institutions or in a single institution. S[illegible]e examples of such arrangements include:

1. A hospital which accepts students from one or more affiliated academic institutions and provides a fourth year composed of professional education.

2. A hospital which accepts only students who have already earned a baccalaureate degree.

3. A university which affiliates with one or more laboratory facilities that provide the clinical portion in the fourth (senior) year of a baccalaureate program.

4. A university which integrates the clinical portion of its baccalaureate program in more than one year of its program curriculum.

5. A program which is individually accredited and is involved also in a consortium under an inter-program agreement.

C. Accreditation is granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and supervised clinical education; appoints faculty to the program; receives and processes applications for admission; and grants the certificate or degree documenting completion of the program. The sponsoring institution shall also be responsible for providing assurance that the activities assigned to students in the clinical setting are educational.

D. Responsibilities for program administration, instruction, and supervision must be clearly described in a written document between the sponsor and each affiliate.

1. An affiliation agreement or memorandum of understanding should encompass the responsibilities of affiliates, faculty, cooperative curriculum development and supervision between academic and clinical facilities.

2. The following types of documents will be considered acceptable as evidence of cooperative curriculum development and supervision:

  a. Minutes, reports, summaries of official meetings between representatives of clinical and academic institutions and/or

  b. Copies of pertinent correspondence between representatives of clinical and academic institutions.

3. Affiliation agreements between hospital or laboratory-based programs and academic affiliates should address and/or include:

  a. Statement that the educational institution will grant a baccalaureate degree or a certificate of satisfactory completion to eligible students.

  b. Criteria for admission, including both academic and non-academic considerations.

  c. Minimum and maximum number of qualified students who may be admitted each year.

  d. Assignment of course numbers and credits to each subject in both academic and professional phases of the program.

  e. Tuition, fees, and the way the monies will be used.

  f. Responsibilities of all of the involved parties.

  g. Policies concerning pass/fail decisions, grading systems, and other evaluation procedures.

  h. Student health policies and services.

  i. Criteria and procedures for reciprocal faculty and staff appointments.

  j. Annual schedule for meetings between instructional staff of the institutions.

  k. Statement providing for periodic review of the affiliation agreement.

4. Affiliation agreements or memoranda of understanding between university-based programs and each of their clinical affiliates should address and/or include:

  a. Supervision of the clinical instruction in the clinical facility.

  b. Number of students to be assigned to the affiliates.

  c. Financial arrangements between institutions.

  d. Student health policies and services.

  e. Criteria and procedures for reciprocal faculty and staff appointments.

  f. Provision for control of the quality of instruction as a responsibility of the accredited program.

  g. Annual schedule for meetings between instructional staff of the institutions.

  h. Statement providing for periodic review of the affiliation agreements.

  i. Responsibilities of each of the involved parties.

5. The number of affiliates and the distance from the parent institution should not adversely affect interaction between the faculty and the program officials.

6. When additional affiliations are negotiated, or significant changes are made in existing affiliations, a copy of the new document should be submitted to the Executive Office of the Cytotechnology Programs Review Committee.

II. RESOURCES

A. General Resources

Resources must be adequate to support the number of students admitted to the program. The instructor/student ratio shall be adequate to achieve the stated objectives of the curriculum.

There should be no more than two (2) students per instructor for the clinical phase of the program. There should be an adequate number of certified cytotechnologists for both the teaching and service load of the laboratory.

B. Personnel

1. Program Officials

The program must have qualified persons designated as program officials. Primary responsibilities shall include program development, organization, administration, evaluation and revision. These responsibilities may be fulfilled in various ways in accordance with institutional policies and practices.

1. Program officials should be able to document that they have enough freedom from other responsibilities to accomplish the day to day teaching, educational and administrative duties of their positions. Freedom from service and other responsibilities may be documented through detailed job

3. *Annual documentation of financial resources of the program should be maintained.*

4. *The practice of maintaining complete records of budget allocations and expenditures for the program is encouraged.*

5. *Program officials should have input into the budgetary process.*

5. **Physical Resources**
   a. **Facilities**
   Adequate classrooms, laboratories, administrative offices, and other necessary facilities shall be provided.

1. *Each student should be provided with an assigned desk and microscope within a properly ventilated laboratory or classroom and with adequate space to evaluate and study cytologic material.*

2. *The laboratory area for the preparation and staining of slides should be large enough to accommodate at least one student in addition to the designated laboratory personnel.*

3. *Space should be provided which may be used for the preparation of lectures, storage of student records, private conferences with individual students, and other administrative duties.*

   b. Equipment and Supplies
   Appropriate modern equipment and supplies, with adequate storage space, shall be provided in sufficient quantities for both didactic and supervised clinical education facilities. Instructional aids, such as clinical materials, reference materials, and demonstration and other multimedia materials must be provided when required by the types of learning experiences delineated in the curriculum for either didactic or supervised clinical education.

1. *Appropriate equipment should include at least one (1) multiviewer microscopic system.*

2. *The instructional personnel and material should be adequate for the instruction of four (4) students per class.*

3. *Appropriate equipment and supplies should be available to both didactic and clinical sites.*

4. *To ensure a well-rounded teaching program, lectures should be supplemented with an adequate supply of instructional aids such as:*

   Normal and abnormal specimens for all body systems examined by the cytopathologic method (study sets)

   Appropriate demonstration and multimedia material

   Sets of selected unmarked slides for microscopic evaluation (unknowns) for development of skills in detection and differential diagnosis

   Medical journals, reprints and texts

For a class of four (4) students, 15,000 cases per year are usually considered the minimum number necessary to provide an adequate learning experience. There should be a balanced non-gynecologic caseload of at least 1,000 cases per year. In addition to specimens from the respiratory tract, specimens from the urinary and gastrointestinal tracts, breast, effusions, cerebrospinal fluid and fine needle aspirates of various organs should be represented. This yearly caseload should include adequate numbers of abnormal cases, particularly in the non-gynecologic area. If affiliated laboratories are used, their volume of material is included for both gynecologic and non-gynecologic specimens. Programs with fewer cases must document that the learning experience for the students is adequate to establish the entry level competencies.

To ensure high quality of diagnosis and completeness of teaching case material for the students, the laboratory should maintain proper indexing, filing, and follow-up systems.

   c. Library
   Students shall have ready access to an adequate supply of current books, periodicals, and other reference materials related to the curriculum.

1. *Library materials should be readily accessible to students within the laboratory setting.*

2. *Budgetary allocations should be made for securing periodicals and books.*

3. *Program officials should have input into the development of the budget and the selection of library acquisitions.*

III. CURRICULUM

A. An acceptable program of instruction shall fulfill the objectives of the program and prepare graduates for entry level competencies in cytotechnology.

1. *The length of the program depends significantly on its organizational structure. As a general rule, at least one calendar year of structured professional instruction in cytotechnology has been necessary to achieve program objectives and to establish entry level competencies.*

2. *Instruction in one institution does not preclude the use of affiliated laboratories. The affiliated laboratories, including their teaching faculty, are part of the program. The sponsoring institution is responsible for the quality of the educational experience in the affiliated laboratories.*

3. *If the program of instruction culminates in a degree, the degree should be of the same academic status as similar degrees given in that institution. Grades and credits for courses should be identified and recorded on the students' transcripts maintained by the sponsoring (academic) institution.*

B. The curriculum shall consist of structured didactic instruction and supervised clinical laboratory experience adequate to meet the approved objectives of the program and to establish entry level competencies.

A complete curriculum of the course of study of the accredited cytotechnology program and its prerequisites should be defined. If the accredited program is fewer than four years, a list of prerequisite courses should be included in the curriculum.

Objectives are clear statements that describe instructional intent in measurable terms of desired learning outcomes. They describe what must be done to demonstrate that the student has achieved what is expected.

1. *The program objectives should include an outline of the program's commitments to the students and a set of descriptions of the graduating student's entry level competencies.*

2. *The curriculum should include all course content commonly offered in a contemporary cytopathology laboratory. Each instructional area must be fully described, including the objectives, lecture outlines and schedules, and laboratory experiences and/or exercises.*

   The curriculum should include principles of pathology and of cytopathologic procedures and diagnosis; structured laboratory sessions and time devoted to practice microscopic evaluations; clinical significance of the cytopathologic diagnosis in the diagnosis and treatment of the patient; and practical components of laboratory management and problem-solving as related to cytotechnology.

made known and available to the students upon admission to the program.

The appeals process should include descriptions of the causes for dismissal, procedures and policies of the institution, and criteria for academic probation.

V. OPERATIONAL POLICIES

A. Fair Practices

1. Announcements and advertising must accurately reflect the program offered.

Catalogues and brochures describing the program should accurately reflect the prerequisites and curriculum. Care should be taken not to mislead the student concerning the educational program, job placement, or income expectation.

2. Student matriculation practices and student and faculty recruitment shall be non-discriminatory with respect to race, color, creed, sex, age, marital status, handicap(s), or national origin.

The objective of the program should be to provide education and training to the student in cytotechnology for a career in that field and gainful employment anywhere, without regard to the specific needs of the laboratory or institution providing the training.

3. Academic credit and costs to the student shall be accurately stated and published and made known to all applicants.

Stipends related to subsequent employment are not acceptable.

4. Policies and procedures for student withdrawal, and refunds of tuition and fees, shall be published and made known to all applicants upon admission.
5. Policies and procedures by which students may perform service while enrolled in the program must be published and made known to all concerned in order to avoid practices in which students are substituted for regular staff. Students may not take the responsibility or the place of qualified staff. However, after demonstrating proficiency, students may be permitted to perform procedures with appropriate supervision. Students may be employed in the field of study outside regular educational hours provided the work does not interfere with regular academic responsibilities. The work must be non-compulsory, paid and subject to employee regulations.

Students may perform laboratory determinations only under competent supervision. Programs conducted primarily for the purpose of substituting students for paid technologists will not be considered for accreditation. Substitution of students for paid technologists by programs already accredited will be considered grounds for withdrawal of accreditation. Indentured back-pay arrangements will be considered unprofessional.

B. Student Records

Satisfactory records shall be maintained for student admission, health, attendance, participation, achievement, and evaluation. Grades and credits for courses shall be recorded on the student transcript and permanently maintained by the sponsoring institution.

The following records should be maintained for each student:

1. *Completed application*
2. *College transcript*
3. *Attendance record*
4. *Academic performance*
5. *Staff evaluations of student's professional attitude and participation in program*
6. *Documents of suspension, leaves of absence, probation or withdrawal, if any*
7. *Record of scholarships, awards, or citations, if any*
8. *Record of graduation*

Records of performance on tests, microscopic evaluations, practicals and other assignments should be maintained during the academic year.

With few exceptions, these records should be kept within the physical facilities of the program. If necessary, duplicate records should be kept in academic institutions.

VI. CONTINUING PROGRAM EVALUATION

A. A process for periodic and systematic review of the program's effectiveness must be documented. The results of these reviews must be considered and reflected in the program's self-study and the *Self-Study Report* required by the accreditation review process.

Effectiveness of the educational program may be documented through periodic review. Review procedures may include:

1. *The assessment of significant aspects through questionnaires, surveys, interviews or other means with faculty, students, graduates of the program, and employers of the graduates.*
2. *A review of the program objectives and means of their implementation and effectiveness by appropriate individuals who are not affiliated with the program. The self-evaluation document prepared for accreditation purposes is recommended for use in monitoring program effectiveness.*
3. *Records of scores on external certifying examination(s) of graduates is an acceptable means of outside evaluation. Such data constitute an important but not the only means of monitoring effectiveness. When examination scores are used for this purpose, identification of individual students must be avoided, in accordance with requirements of privacy laws.*

B. The results of program evaluation must be appropriately reflected in review of the curriculum and other elements of the program, with appropriate revision.

MAINTAINING AND ADMINISTERING ACCREDITATION

A. Program/Sponsoring Institution Responsibilities

1. Applying for Accreditation

The accreditation review process can be initiated only at the written request of the chief executive officer or an officially designated representative of the sponsoring institution.

This process is initiated by requesting an application form from and returning it to:

Department of Allied Health Education and Accreditation
American Medical Association
535 N Dearborn Street
Chicago IL 60610

Review committees may request additional application materials prior to guiding the program through completion of a self-study and submission of a *Self-Study Report*.

Recent Survey of Cytotechnology Training Programs

Lorri J. Genack, CT(ASCP), and G. Berry Schumann, MD

This survey study was designed to assess the status of cytotechnology training programs, address the issue of student recruitment, and elicit suggestions for improved programs from cytotechnology educators. Questionnaires were completed by 56 program directors/educational coordinators of accredited cytotechnology programs. While practical guidelines for existing cytotechnology training programs are available, the results of this survey confirm the need for more information and discussion regarding the changes needed to strengthen the future of educational programs for cytotechnology professionals.

Cytotechnology is a distinct and highly specialized allied health profession. The trained cytotechnologist, under the direction of a pathologist, is responsible for the microscopic recognition, identification, and interpretation of detailed morphologic features of normal and abnormal cells from multiple body sites. Because of the increased clinical acceptance and utilization of cytopathology in the detection of malignant and premalignant disease, cytotechnology program directors and instructors must reevaluate and address the changing and increasing responsibilities of this discipline.

There has been a steady decline in the number of accredited cytotechnology training programs in the United States since 1970 (Fig 1). During the 1983-84 school year, there were 66 programs in 34 states (Fig 2). Notably, only six programs were located in the Western region. Decrease in the quality of student applicants was cited as a problem by inactive and closing programs.

This survey study was designed to assess the status of current training programs, address the issue of student recruitment, and elicit suggestions for improved programs from cytotechnology educators. Table I lists the specific questions addressed in the survey.

Materials and Methods

This study was conducted in four stages: questionnaire development, pilot testing of questionnaires, survey of remainder of study population, and data analysis. The population studied included program directors/educational coordinators of 66 accredited cytotechnology programs, as listed in the cytotechnology literature.[1] A pilot survey, accompanied by a cover letter and stamped, self-addressed return envelope, was mailed to the program directors/educational coordinators of six of these programs. Four of six pilot surveys were completed and returned within two weeks. Respondents indicated that no questionnaire modifications were necessary. One week after pilot surveys were mailed, presurvey letters were mailed to the 60 other program directors/educational coordinators, informing them of the forthcoming survey. The remaining 60 questionnaires, cover letters, and return envelopes were mailed following receipt of two thirds of the pilot surveys. Within one month, 43 (72%) of these surveys had been returned. Letters of reminder and additional copies of the questionnaire were mailed to noncompliant programs. Of 19 second surveys mailed, nine were returned within two weeks. Data were then compiled and analyzed.

Results

Of 66 programs surveyed, 56 re-

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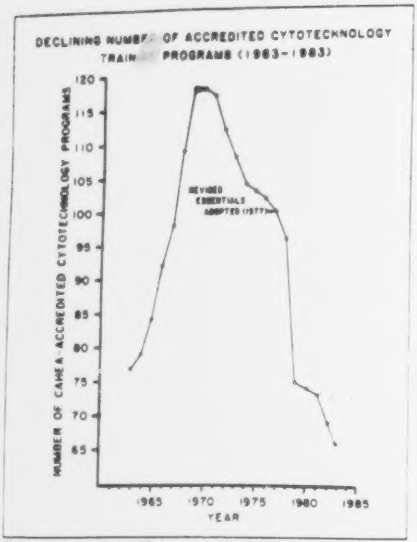

Fig 1 Number of CAHEA-accredited cytotechnology programs

Table I: Items Addressed by Questionnaire

1. How many of the programs are inactive*/closed? What are their reasons for inactivity/closure?
2. How many of the active programs grant a degree or have a degree option for students completing their programs? What types of degrees are they offered?
3. How many of the active programs grant a certificate only upon completion? How do these programs intend to comply with the ASCP degree requirement, effective 1988?
4. How many programs are longer than the traditional 12 months?
5. What is the percentage breakdown of program applicants, with regard to location, sex, and age? When do applicants seek entry to the program?
6. In 1982, 1983, and 1984, what were the ranges and average numbers of applicants? In 1982, 1983, and 1984, what were the ranges and numbers of students accepted to the programs?
7. To what extent is recruitment perceived as a difficulty by program directors/educational coordinators?
8. What are the educators' suggestions for the design of an "ideal" training program?

*Accredited, but no students currently enrolled

sponded for an overall response rate of 85%.

Status of Current Training Programs

Of 56 respondents, 46 (82%) were active, nine (16%) were inactive, and one program was closed. Two active programs reported that they would be inactive in 1985-86. One of these programs did not complete the rest of the questionnaire. Of ten inactive/closed programs, six cited a single reason and four cited two reasons for their current status (Table II).

Forty-five active programs submitted completed questionnaires. Of these, nine were baccalaureate degree-granting, 15 had a degree/certificate option, and 21 were certificate-granting. Thus, a total of 24 programs (53%) conferred a baccalaureate degree or had a degree option. Types of degrees are listed in Table II.

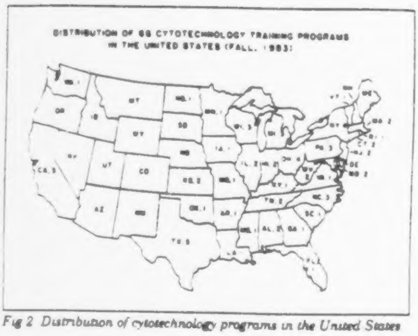
DISTRIBUTION OF 66 CYTOTECHNOLOGY TRAINING PROGRAMS IN THE UNITED STATES (FALL, 1983)
CA 5
OR
ID
MT
WY
UT
CO
AZ
SD
KS 2
IA 1
OK 1
AR 1
TX 5
TN 2
NC 3
SC 1
GA 1
PA 3
CT 2
DE
NY
VT
ME

Fig 2 Distribution of cytotechnology programs in the United States

The remaining 21 active respondents granted a certificate only to students completing their programs. Effective 1988, the American Society of Clinical Pathologists (ASCP) will require that students have a baccalaureate degree in order to be eligible for the Cytotechnologist, CT(ASCP) examination. Fourteen (67%) of the certificate-granting programs stated an intention to comply with this new requirement by accepting students already holding a degree (Table II). Four programs plan to both accept students with degrees and become affiliated with a university. None of the programs stated an intention to close due to the new degree requirement. Additional mechanisms of compliance are presented in Table II.

A majority (87%) of the active respondents had 12-month programs. Six (13%) of the programs were longer than the traditional 12 months, ranging from 14 to 24 months (Table II). Five of the expanded programs granted degrees. The 14-month program offered a certificate with an option to continue for two additional years and receive a BS degree in Health Administration or Health Education.

Recruitment

Program directors/educational coordinators were asked to describe the location, sex, and age of their applicants using approximate percentages (Table III). Results indicated that the majority of applicants were located in-state (75%), female (74%), and between the ages of 21 and 25 years (58%). A majority of applicants (56%) sought entry to the programs after two

Table II: Status of Current Training Programs

Reasons for inactivity/closure
4 (40%) are redesigning their programs.
4 (40%) had lack of funding.
3 (30%) responded to [illegible] of cytotechnologists in the area.
2 (20%) had difficulty re[illegible]ing students.
2 (20%) had lack of [illegible]ologist support.
Types of baccalaureate degrees offered
13 Cytotechnology
6 Clinical Laboratory Science/Allied Health
1 Medical Technology
1 Biology
2 Dependent upon affiliate colleges
1 Student-designed with cytotechnology concentration
Mechanisms of compliance with degree requirement
14 (67%) will accept students already holding a degree.
6 (28%) will affiliate with a university to provide a degree.
3 (14%) will convert to a degree program.
2 (10%) are undecided.
Length of programs
39 (87%) 12 months
1 (2%) 14 months
2 (4%) 18 months
1 (2%) 21 months*
1 (2%) 22 months
1 (2%) 24 months

*This program also offers a 12 month post-baccalaureate certificate program.

to three years of previous college education. When only the degree and degree-option programs were considered, this number increased to 68%. Certificate programs reported that 47% of the applicants applied for entry immediately or within one year of completing a baccalaureate degree.

The mean numbers of students who applied and were accepted to the programs for 1982, 1983, and 1984 are presented in Table IV. During this three-year period, an overall average of 11 students applied per year and six were accepted, for a ratio of 1.8/1.

Table IV compares mean number of applicants and students accepted for the different types of programs. While the mean numbers appear similar from year to year and between types of programs, the range of individual responses indicates wide variation.

Recruitment of qualified applicants was somewhat to moderately difficult according to a majority (71%) of respondents (Table V). Programs were separated by their response to the preceding question and analyzed for ratio of applicants/accepted students for 1984 (Table V). Generally, respondents who perceived recruitment as not difficult reported higher ratios of applicants/accepted students than those who considered recruitment to be very difficult. Interestingly, data from certificate programs indicated a nearly opposite pattern.

A wide range of recruitment activities was reported by the respondents (Table VI). The majority of programs (91%) employed more than one technique. Distribution of brochures, attendance at career days/open houses/health fairs, recruitment assistance by college advisors or admissions officers, and presentation of recruitment lectures were the predominate activities.

Suggested Characteristics of an Ideal Program

The final question of the survey asked respondents to describe the type of cytotechnology program they would design if they had unlimited resources. Of 56 respondents, 45 (80%) completed the question. Responses, listed under broad categories, are presented in Table VII. Three individuals stated that their programs were ideal and therefore they wouldn't change anything. The remaining 42 responses included a wide range of suggestions. Of 23 respondents commenting on program length, 15 (65%) indicated that their "ideal" program

Table III: Location, Sex, and Age of Applicants

Questions	Type of Program (%)			
	Total (N = 45)	Degree (N = 9)	Degree Certificate (N = 15)	Certificate (N = 21)
Who are the applicants?				
Location				
In-state	75	89	80	60
Out of state	15	7	17	23
Foreign	7	4	3	7
Military enlisted	3			10
Sex				
M	26	25	28	25
F	74	75	72	75
Age, yr				
18-20	16	24	16	9
21-25	58	51	65	59
26-30	17	17	12	22
>31	9	8	7	10
When do applicants seek entry to the programs?				
After 2 to 3 yr previous college education	56	72	64	33
Immediate or within 1 yr of completing a baccalaureate degree	27	14	21	47
Within 2 to 5 yr of completing a baccalaureate degree	11	8	11	14
>5 yr after receiving a baccalaureate degree	5	6	4	6

Table IV: Data on Applicants and Accepted Students

Year		No. (Range) Applied	No. (Range) Accepted	Ratio
Mean No. of Applicants and Accepted Students for All Respondents (1982-1984)				
1982		9	6	1.5/1
1983		12	6	2.0/1
1984		11	5	2.2/1
Mean No. and Ranges of Applicants and Accepted Students (1982-1984)				
1982	Degree	13 (6–30)	7 (2–21)	1.9/1
	Degree/certificate	8 (3–17)	4 (1–8)	2.0/1
	Certificate	7 (1–40)	6 (1–15)	1.2/1
1983	Degree	14 (4–25)	7 (2–11)	2.0/1
	Degree/certificate	8 (4–18)	4 (1–8)	2.0/1
	Certificate	13 (3–30)	6 (3–15)	2.2/1
1984	Degree	13 (2–36)	6 (0–19)	2.2/1
	Degree/certificate	7 (4–13)	4 (0–8)	1.8/1
	Certificate	13 (3–33)	5 (3–13)	2.6/1

would be longer than 12 months, seven (30%) stated that 12 months was adequate, and one would shorten the program to 11 months. Seventeen programs commented on class size. Two (12%) favored ten to 12 students per class, five (29%) favored six to eight students per class, and five (29%) favored four to five students per class. Three (18%) preferred more than four students, but did not further specify, and two (12%) favored a decrease to one to two students.

The most common assertion by respondents was the need to broaden the program of study to include training in other subjects and disciplines. Histology histotechnology and fine-needle aspiration cytology were the courses most frequently mentioned.

Six statements related to clinical affiliations. Five (83%) indicated a need for increased number and types of affiliates, and one described the need for affiliates located throughout the state or region.

Eighteen comments related to personnel matters. Increasing the number of faculty and staff associated with the schools was the most frequent suggestion made by respondents in this area. Ten statements specified the need for increased and improved educational aids and equipment. Of six comments relating to finances, three were concerned with the establishment of a fund for continuing education.

Discussion

At a time when existing cytotechnology training programs are closing and new regulations are being im-

Table V: Recruitment of Applicants

	Type of Program, No. (%)			
	Total (N = 45)	Degree (N = 9)	Degree/Certificate (N = 15)	Certificate (N = 21)
To what extent is the recruitment of qualified applicants a difficulty for the program?				
Not a problem	6 (13)		2 (13)	4 (19)
Somewhat difficult	17 (38)	4 (44)	6 (40)	7 (33)
Moderately difficult	15 (33)	4 (44)	5 (33)	6 (29)
Very difficult	7 (16)	1 (12)	2 (13)	4 (19)
Program response (No. applied/No. accepted)				
Not a problem	3/1		4.5/1	1.4/1
Somewhat difficult	2.5/1	2.6/1	2.1/1	2.7 1
Moderately difficult	2.4/1	1.7/1	1.9/1	3.6 1
Very difficult	1.6/1	1 1	1 7 1	2.1 1

Table VI: Recruitment Activities

	Type of Program, No. (%)			
Activities	Total (N = 45)	Degree (N = 9)	Degree Certificate (N = 15)	Certificate (N = 21)
Brochures	35 (78)	8 (89)	11 (73)	16 (76)
Career days/open house/health fairs	34 (76)	8 (89)	13 (87)	13 (62)
Recruitment by college advisors/admissions	34 (76)	8 (89)	12 (80)	14 (67)
Recruitment lectures	28 (58)	8 (89)	9 (60)	9 (43)
Posters in high schools/colleges	12 (27)	4 (44)	2 (13)	6 (29)
Newspaper ads	12 (27)			12 (57)
Word of mouth	2 (4)			2 (10)
Recruitment films	2 (4)	2 (22)		
Participation in allied health careers class	2 (4)	1 (11)	1 (7)	
Counsel or workshops	1 (2)	1 (11)		
Phonathons	1 (2)	1 (11)		
Guaranteed admission—high school seniors	1 (2)	1 (11)		
Military directives	1 (2)			1 (5)
Recruitment of college biology majors	1 (2)	1 (11)		
Information available on computerized information system	1 (2)			1 (5)
Review of hospital personnel files—information sent to qualified potential candidates	1 (2)			1 (5)

Table VII: Suggestions for an "Ideal" Cytotechnology Training Program

	Type of Program			
	Total (N = 48)	Degree (N = 9)	Degree/Certificate (N = 18)	Certificate (N = 21)
Wouldn't change anything—program is ideal	3		1	2
Length of Program				
Maintain 12-month length	7	1	2	4
Increase length of program	15	5	4	6
Shorten program to 11 months	1		1	
Integrate CT courses into 4-yr program	1			1
Integrate practical and didactic training	1			1
2-mo break/yr for preparation of materials			1	1
Multidisciplinary master's degree option	2	2		
Class Size				
1 to 2 students/class	2		1	1
4 to 5 students/class	5	1	2	2
More than 4 students/class (not further specified)	3	2		1
6 to 8 students/class	5		2	3
10 to 12 students/class	2	1		1
Students				
Increase entry requirements in biology/chemistry		1		1
Increase entry requirements to include embryology, histology, anatomy	1			1
Recruit at high school level	1			1
Courses/Program Emphasis				
Increase training in other disciplines	20	5	5	10
histology/histotechnology—11				
electron microscopy—4				
fine-needle aspirations—5				
management/supervision—5				
research—4				
special techniques (immuno/cell image analysis/cytochemistry)—6				
computer studies—3				
cytogenetics—2				
Increase No. of lectures/lectures by clinicians	4		3	1
Cooperative projects with medical technology students	1		1	
Increase emphasis on screening	4	1	1	2
Increase supplemental reading	1		1	
Increase No./types of clinical affiliates	5	3	2	
Widespread clinical affiliates	1		1	
Adequate volume of clinical material	2			2
Personnel				
Faculty designated solely for school	2		1	1
Additional faculty/staff for school	9	4	3	2
Increased input from pathology/pathology residents	4	2		2
Coordination with residency training program	1	1		
Instructors teach in their specialty area	1			1
Better defined faculty roles/responsibilities	1			1
Educational Aids/Equipment				
Increase visual aids/color plates/textbooks	3		2	1
Multiheaded microscope solely for school use	3	1	1	1
Projectors and video equipment	2		1	1
Photomicroscopy equipment	1	1		
Computer-assisted instruction	1	1		
Finances				
Establish fund for continuing education	3	2	1	
Increase budget	1		1	
Remuneration for instructors	1	1		
Offer stipends	1		1	
Miscellaneous				
Adequate physical facilities	2	1		1
Less regulatory input from ASC	1		1	
Nationwide public education program for recruitment	1	1		
Regional training centers with large number of students	2	1		1

posed, institutions involved in designing new educational programs face serious considerations. Unfortunately, information related to the education of cytotechnologists is limited. Accreditation agencies such as the American Society of Cytology (ASC) and ASCP establish minimum standards and operating guidelines. Program Faculty Seminars sponsored annually by the ASC provide guidance in areas of practical concern to existing training programs, such as: compliance with the ASCP degree requirement, revisions in program essentials, affiliation agreements, developing examinations, and establishing continuing education programs. Recent articles have addressed the practice of cytotechnology and its relationship to the cytotechnology program curricula.[2-4]

In contrast to information currently available, this report provides information about cytotechnology program status, student recruitment, and suggestions for program improvement. The steady decline of training programs since 1970 is a significant concern. While the effect of the imminent ASCP degree requirement on the status of cytotechnology programs is undetermined, none of the programs responding to the survey stated an intention to close because of this new regulation.

Of interest to us was the geographic distribution of programs (Fig 2). Of six programs operating in the western United States, four responded to the questionnaire. Of these, three programs were active and one was inactive. Two of the active programs were certificate-granting and stated an intention to comply with the ASCP degree requirement by accepting students already holding a degree. The remaining active program conferred a degree in cytotechnology. From 1982 to 1984, the overall ratio of applicants/accepted students for these three programs was 3.3/1, in contrast to the ratio of 1.8/1 for all programs.

A comprehensive and successful recruitment plan is an important component of any educational program. A 1982 article on cytotechnology student recruitment commented on the increased need for formal recruitment efforts and detailed several methods of recruitment.[5] While our survey results indicated that programs have employed a variety of recruitment methods, the overall ratio of applicants accepted students from 1982 to 1984 was only 1.8/1. Results of a recent survey of program directors conducted under the aegis of Committee on Allied Health Education and Accreditation (CAHEA) indicated that while 66% of respondents believed the job market offered graduates appropriate responsibilities, almost half (47%) believed the income was not appropriate. Furthermore, 29% of respondents believed the job market did not offer graduates an attractive opportunity and 24% were not sure.[6] This information certainly has implications in recruitment of students and may in part explain the low applicant figures.

Many of the educators surveyed provided suggestions for an "ideal" cytotechnology program. Results indicated that a majority of respondents favored a program longer than 12 months, with broadened and interdisciplinary curricula and a class size of more than four students. Specific needs relating to clinical affiliations, personnel, and educational aids and equipment were frequently described (Table VII).

While practical guidelines for existing cytotechnology training programs are available, the results of this survey confirm the need for more information and discussion regarding the changes needed to strengthen the future of educational programs for cytotechnology professionals.

Addendum

Since competition of our study, a recent telephone survey by the Programs Review Committee, American Society of Cytology revealed that there were 51 active cytotechnology programs as of July 1985.[7]

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ASCT
AMERICAN SOCIETY FOR CYTOTECHNOLOGY

CODE OF ETHICS, GUIDELINES FOR THE ETHICAL PRACTICE OF CYTOTECHNOLOGY AND BY-LAWS

CODE OF ETHICS

Being thoroughly cognizant of my committment to the practice and delivery of exemplary health care services in Cytotechnology, I affirm and insure my dedication to the performance of my professional duties with accuracy, thoughtfulness, and care.

Recognizing that the welfare of the community and individual patient is a principal element of my profession, I shall approach each professional task with the utmost reliability and application of highest interpretive standards and shall hold inviolate the trust placed in me by patients and physicians.

(Adopted by the Executive Council, April, 1981.)

GUIDELINES FOR THE ETHICAL PRACTICE OF CYTOTECHNOLOGY

These guidelines are to accompany the Code of Ethics and are to assist cytotechnologists in the proper conduct of their profession.

(Adopted by the Executive Council, April, 1982.)

1. The cytotechnologist makes the final cytologic interpretation for gynecologic cell samples which are within normal limits and makes the preliminary cytologic interpretation for abnormal gynecologic and all non-gynecologic cell samples under the general direction of a qualified pathologist. The cytotechnologist should:

    - verify the identification of the specimen.
    - determine and record the adequacy and quality of the specimen.
    - be aware of technical limitations and the possibility of procedural error.
    - thoroughly examine the cell sample microscopically.
    - compare the microscopic findings with recognized cytomorphologic criteria.
    - consider the clinical data of the patient and compare these data with the microscopic findings.
    - review various diagnostic possibilities, taking into account normal cellular patterns, the presence of microorganisms, inflammatory reactions, endocrinopathies, benign atypias, premalignant changes, benign and malignant neoplasms, cellular responses to therapeutic agents, etc.
    - make a cytologic interpretation.
    - write a report using recognized cytopathologic/histopathologic terminology for gynecologic cell samples which are within normal limits.
    - write a final report of abnormal cytologic findings following joint evaluation of the cellular sample by the cytotechnologist and the qualified pathologist.

2. The cytotechnologist understands that responsibility to the patient supersedes responsibility to all others. The cytotechnologist should:

    - place the welfare of the patient above personal consideration.

3. In acting in a professional manner, the cytotechnologist should:

   - exercise ethical judgment in decision making processes, accept the responsibility for the consequences of those decisions and be able to acknowledge personal error.
   - abide by the rules and regulations of the laboratory or institution.

4. The cytotechnologist possesses professional credentials by being registered as a cytotechnologist by a recognized agency.

5. The cytotechnologist adheres to current established quality control guidelines in all phases of the laboratory operation. The cytotechnologist should:

   - not willingly assent to employment where the workload is excessive or where other factors do not permit adequate evaluation of specimens.

6. The cytotechnologist participates in continuing education programs in cytopathology in order to maintain high standards of proficiency. The cytotechnologist should:

   - attend local, regional, national or international meetings.
   - participate in self-assessment programs when available and review current journals and newsletters containing cytologic articles.

7. The cytotechnologist uses the principles of specimen collection, cytopreparatory methods and laboratory safety in order to maintain an effective laboratory operation. The cytotechnologist should:

   - ensure that specimens are correctly labeled.
   - be knowledgable and competent in the principles, techniques and instrumentation of cytopreparatory methods.
   - process cytologic specimens accurately using methods which will ensure maximum cellular recovery.
   - be able to perform or to direct the performance of laboratory procedures according to the priorities of efficient patient care.
   - assume responsibility for the identification and correction of unexpected as well as frequently occuring problems.
   - maintain a safe environment for persons in the laboratory.

8. The cytotechnologist is familiar with the principles of the organization of a cytopathology laboratory and cytopathology laboratory data systems. The cytotechnologist should:

   * have a basic understainding of the personnel structure of a laboratory, operating within a budget, and the interaction of the cytopathology laboratory with other medical facilities.
   * have a basic knowledge of data collection and retrieval systems necessary to ensure efficient, accurate reporting of laboratory results.

9. The cytotechnologist collaborates with the pathologist, other physicians and allied health professionals in providing effective health care for the patient. The cytotechnologist should:

   * effectively convey information to those professionals directly responsible for patient care so that they understand how to request specific examinations, know when to expect appropriate results, and understand the reason for any request for additional clinical data or repeat sampling.
   * keep all information concerning the patient confidential.
   * recognize and respect the role of both the patient's physician and the laboratory director in the diagnostic interpretation of laboratory data and treatment of the patient.

POSITION DESCRIPTION FOR CYTOTECHNOLOGIST

I. Major Duties

Serves as cytotechnologist in the Anatomical Pathology Service of a medical center laboratory with the responsibility for performing a full range of procedures including the cytodiagnosis of benign and malignant conditions as seen in sputum; respiratory, gastrointestinal and urinary tract washings and brushings; urine, body fluids and cerebrospinal fluid; uterine, cervical and vaginal smears; needle aspirations; tumors and tissue imprints. The technologist will identify all unusual findings in the preparations such as the presence of bacteria, fungi, viruses, yeasts, parasites, and changes secondary to therapy, nutritional disorders, etc. The results of the work are used as a reference for continued patient screening, clinical diagnosis, therapeutic decision and monitoring.

- Examines and evaluates the cell sample for the presence or absence of normal/abnormal cellular patterns, presence of microorganisms, inflammatory reactions, endocrinopathies, benign changes, pre-malignant changes, neoplasia and cellular responses to therapeutic agents. Assesses non-malignant or borderline cellular changes of benign lesions and determines type e.g. inflammatory versus dysplasia versus hyperplasia and/or determines possible cause. Evaluates dysplastic changes and determines grade or severity of process and cell type. Assesses malignant cell morphology and on the basis of diagnostic criteria determines cell or tissue type, differentiation of the neoplasm and when possible primary site of the neoplasm.
- Determines whether cellular changes meet guidelines to necessitate referral to pathologist.
- Prepares written cytopathologic diagnostic reports using recognized cytopathologic/histopathologic terminology and makes recommendations for further evaluation or treatment.
- Relates cytomorphologic changes to clinical data.
- Conveys diagnosis to those professionals directly responsible for patient care using appropriate terminology.
- Evaluates and/or determines the proper technical procedure appropriate in the preparation of specific cytology specimens.
- Conveys information to those professionals directly responsible for patient care in regard to proper collection methods, transportation of specimens, interpretation of reports, etc.
- Receives specimens and accompanying requisition and reviews for completeness and accuracy.
- Accession specimens, determining adequacy and quality of specimen prior to recording the data in the appropriate log book or computer.
- Processes and prepares all specimens for cytodiagnostic procedures while controlling physical conditions and responding to time factors to insure that the physiological state of the specimen is maintained. This includes the use of the centrifuge, cytocentrifuges, filtration techniques, (both cellulosic and non-cellulosic filters),cell block methods, etc.
- Utilizes appropriate fixation and staining techniques to include but not limited to Papanicolaou staining technique and monitors and labels slides according to professional quality control methods.
- Develops and maintains procedures for introduction into the Operations Manual. Modifies existing procedures as they need change.

- Acknowledges technical limitations and various possibilites for procedural errors in cytopreparation. Takes corrective action.
- Evaluates, prepares and selects reagents, supplies and equipment; establishes and maintains inventory control.
- Operates, maintains and troubleshoots all equipment in the cytopathology laboratory.
- Establishes and defines quality control procedures to determine accuracy of cytologicl diagnoses and quality and appropriateness of cytopreparatory techniques.
- Assures proper storage and maintenance of all cytology records to include slide files, report files, billing records, etc. whether on manual or computerized systems.
- Assists with specimen collection and preparation obtained by special procedures such as fine needle aspiration and endoscopic brush.
- Maintains cytotechnologist screening workload statistics and other workload data and prepares annual reports using the College of American Pathologists or AMIS workload recording method.
- Instructs cytotechnology students and residents in cytopreparatory techniques and diagnostic criteria. Participates in the presentation of papers and microscopic workshops at professional meetings of cytotechnologists and physicians.
- Remains current in the field by review of cytologic periodicals, attending professional society meetings and other continuing education programs, as appropriate.

II. Factor 1: Knowledge Required by the Position

- Professional knowledge of cytotechnology principles, concepts and methodology sufficient to perform a broad range of tests, including non-routine analysis. Knowledge of body systems to facilitate the evaluation of specimens obtained by a variety of techniques to include fine needle aspiration of major organ systems and subcutaneous masses. Understand the relationship between relevant clinical data and a variety of complex, similar, yet different often overlapping morphological changes and criteria to arrive at an accurate diagnostic judgment and recommendation. Understand the anatomy, function and physiology of all body sites and of the cells and cell functions native to these sites as well as normal and abnormal cellular changes which might accur.
- Knowledge and skills to interpret the various clinical presentations of disease and apply such knowledge in conjunction with the microscopic findings to affect an appropriate and accurate final diagnosis.
- Knowledge sufficient to check correlation and validity of results.
- Knowledge and skills sufficient to select, adapt or design techniques to optimize the quality of specimen preparations.
- Knowledge of accrediting/regulatory agency requirements sufficiently to insure that work is consistent with standards.
- Knowledge and skills sufficient to provide technical instructions on problems and advise other departments on cytologic techniques.

III. Factor 2: Supervisory Controls

- Performs diagnostic and technical functions independently within the structure of the Anatomical Pathology section of the laboratory and as such

1. determines overall objectives and resources of the unit.
2. plans and organizes the daily workload.
3. determines approach to be taken and methodology to be used.
4. resolves problems and corrects technical errors.
5. develops techniques.

- completed work is reviewed from an overall standpoint in terms of feasibility, compatability with other work and effectiveness in meeting requirements or expected results.

IV. Factor 3: Guidelines

- Sources of guidelines include texts, journals, periodicals, laboratory manuals, professional organizations (CAP, JCAH, ASCP, ASC, IAC), professional seminars, workshops and meetings, as well as academic background, training and experience.
- Scope of judgment includes subjective microscopic evaluations based on uniquely individual combinations of academic instruction, technical training, quality and quantity of experience and combinations of knowledge and skills, as well as prioritizing guideline sources and interpreting applicability in matters of specimens identification, processing, recording and quality control:— Selecting, adapting or designing procedures and methods in response to hospital and laboratory considerations and organizing this information for incorporation into the laboratory manual.

V. Factor 4: Complexity

Diagnostic functions include a daily detailed synthesis of different combinations of clinical histories, medications, therapies, oncology, microbiology, anatomy, physiology, histology, cytology and pathology to affect final cytologic diagnosis on each cell sample. As such the cytotechnologist must

- provide the pathologist with a reasonable judgment regarding the presence or absence of malignant cells, cell type, probable site of origin and probable degree of histologic differentiation.
- design an appropriate surveillance system for quality control.
- design and implement a program for instructing and updating laboratory personnel, nursing staff and physicians in cytologic technique.
- establish and implement procedures in the identification, collection, preservation, preparation and staining of specimens through experience, research, study and experimentation.
- assume full responsibility for the technical aspects of cytopreparation and problem solving in the unit.
- understand cellular and staining reaction chemistry, fixation techniques and their application in order to adequately prepare diverse cell samples for microscopic evaluation.
- establish priorities in specimen processing according to laboratory guidelines and clinical considerations.
- correlate diagnostic reports of surgical specimens with diagnostic reports of cellular specimens as a means of quality control for the microscopic evaluations rendered.
- assess adequacy of each sample, evaluate ancillary data provided and determine if additional information and/or testing is necessary, then implement the required procedures to affect a change.

VI. Factor 5: Scope and Effect

The purpose of the position is to perform a variety of cytologic tests (qualitative and quantitative) on a variety of cell samples for the presence or absence of cancer, infectious disease and other cellular abnormalites and to provide accurate test results to physicians in a timely manner.

The work of the cytotechnologist directly affects the efficiency and effectiveness of laboratory operations and the ability of the laboratory to meet the needs of the patients as is determined by the medical staff.

VII. Factor 6: Personal Contacts

Personal contacts are with physicians, students, nurses, patients, scientists and other disciplines, medical technologists and technicians in other sections of the laboratory and laboratory inspection teams.

VIII. Factor 7: Purpose of Contacts

The purpose of contacts is to obtain clinical information, advise on test results, resolve testing problems, explain selected methodologies, instruct physicians, nursing staff and resident staff in proper specimen collection, explain cytomorphologic criteria and assist in selected special procedures.

IX. Factor 8: Physical Demands

Physical demands require many hours of bending over a microscope. Manual dexterity, visual acuity and color vision and the ability to sit and concentrate for long periods of time are physical requirements.

X. Factor 9: Work Environment

The work environment includes moderate risks with regular and recurrent exposure to potentially carcinogenic and highly infectious microbial agents e.g., tuberculosis, coccidioidomycosis, specimens from patients diagnosed as having AIDS, etc. Safety precautions and protective clothing or gear are required to be used e.g., laboratory coats, gloves and a biohazard hood.

Special Report from the Professional Standards and Practices Committee and the Executive Council of ASCT:

ASCT Guidelines for the Practice of Diagnostic Cytology

Stage I

Cytotechnologist Workload

In May of 1986 the Professional Standards and Practices Committee was charged with implementing a study to determine whether or not ASCT should establish guidelines for the practice of diagnostic cytology and, if so, what those guidelines should be. The committee decided to divide this important and complex subject into a series of small studies, each covering a different aspect of quality assurance. The first problem selected for study was diagnostic workload for cytotechnologists.

The study

The proposed method of study was by Delphi Poll, a problem-solving tool that serves to generate ideas and at the same time allows an expert panel to evaluate their merit. What is looked for in a Delphi poll is confluence of opinion; not absolute agreement, but a moderation of extreme views toward a mean on subsequent rounds after feedback has caused reconsideration of a problem. Anonymity is preserved so that ideas are judged on their own merit rather than by the prestige of the person generating them.

Survey questions were written in the form of a ballot and sent to twelve members of ASCT by one person acting as a monitor. (These experts were chosen from past and present members of the Executive Council.) The completed ballots along with related pro and con written statements were returned to the monitor. The monitor tabulated the answers, recorded the statements, and mailed the results together with a new ballot back to panelists for reconsideration. The new ballots were completed and returned to the monitor. Two rounds were enough to complete this study.

The Executive Council of ASCT examined the results of the Delphi Poll at the ASCT Annual Meeting in San Diego, California in June, 1987. The Council agreed to present the proposed recommendations to you, the general membership of ASCT, for your comments and suggestions. Please note that these proposed recommendations are printed here for review, but *they are not yet final recommendations.*

Proposed recommendations for cytotechnologist workload

A recommended slide workload for experienced cytotechnologists performing microscopic work with no other duties:*

DAILY**

Gyn	80 slides per day (range: 70-90)
Nongyn	50 slides per day (range: 40-60)

- *Workload time includes daily consultation, research, patient history gathering and discussion time as well as time at the microscope.*
- *Daily workload, with rare exceptions, should not exceed the maximum recommended amount in order to assure the maintenance of quality work.*
- *Cytotechnologists should be allowed appropriate break time (lunch, sign-out, etc.) during periods of concentrated microscopic work.*
- *Four cytocentrifuge slides equal one smeared slide in examination time. Recommendations are for smeared slides.*

*A 24 hour period.

We, the members of the Executive Council of ASCT, recognize that there exists a range of cytotechnologist capabilities due to individual mental and physical differences, as well as levels of experience. We think that the workload recommendations accommodate these differences.

Why do we need workload recommendations?

Because . . . workload figures provide guidelines for staffing and personnel standards of laboratories.

Because . . . some cytotechnologists are forced to work beyond a reasonable capacity for their pay in order to keep or advance in their jobs or to earn a living wage (see ASCT Quality Control Survey Report, *ASCT News*, Vol. VI, No. 7, 1985). Quantitative guidelines are a needed first step in the direction of protection.

Because . . . restraints are needed in the name of public safety. Just as the public needs protection from fatigued truck drivers, despite these workers' cries of protest about reduced earnings, so it needs protection against life- threatening mistakes in the laboratory by overburdened personnel. Workload figures are one objective measuring stick that could be used by outside observers in judging a laboratory.

Because . . . it is unethical practice to work beyond one's ability for the purpose of increasing wages. Shouldn't cytotechnologists and pathologists who do this be held accountable?

Workload . . . *continued from page 75*

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*One year or more experience.

Workload ... *continued from page 65*

Because ... if ASCT is to be an official voice and standard-setter for the profession of cytotechnology, it is essential that we generate reasonable and acceptable work and performance standards.

What do you think?

If you disagree with us on this issue, we need to know what your objections are and why, in as much detail as possible. This is a chance to make a difference to your profession in a matter that may some day be up for legislation. If you are happy with what we are doing we want to know that, too.

Please address all comments to: Jean Triol, CT, Chair, Professional Standards and Practices Committee, 11 Spokane Lane, Somerville, N.J. 08876.

jbt

Article summarizing ASCT's activities regarding Quality Practice
in Cytotechnology
to be published in January, 1988 issue of
ASCT News

Amidst the recent flurry of media attention to the accuracy of Pap smear testing and the cytotechnologists' role in this evaluation, ASCT officials and members have been busy representing the interests of cytotechnologists. Legislative Consultant Patricia Ashton has spearheaded this effort to guarantee that cytotechnologists have input into any government legislation or activity which will affect the practice of cytology. Pat has devoted an enormous amount of time answering inquiries from sources nationwide about the profession and the problems currently surrounding cytotechnology. The calls have been so numerous that it has become necessary to install an answering service in Washington D.C. to more efficiently handle responses and channel information to the appropriate sources in the Society.

As you are aware from her legislative issues of the *ASCT News*, Pat is constantly in touch with people in Washington who alert her to any activity which may have an impact on cytotechnology. Finding out that HCFA was again accepting bids for a contract to inspect cytology laboratories receiving Medicare reimbursement, ASCT responded accordingly by submitting a bid in September, 1987. With contributions from many ASCT members, Pat and Past-President Shirley Greening engineered the development of this proposal which included a "criteria document" defining acceptable standards for every aspect of the cytology laboratory. President Carol Trew assisted them in this effort. It was an awesome task to which we devoted countless hours. ASCT currently awaits word from HCFA on its decision, which reportedly will now be announced in February.

In November, Pat learned that two Washington Senators were investigating problems surrounding inaccurate Pap smear results and arranged for us to meet with their aides. The purpose of these meetings was to explain that ASCT is an organization of cytotechnologists with a nationwide communication network that has access to a large body of knowledge about the profession which would be beneficial to their investigation. The Senators' staff members expressed interest in any information ASCT could provide about this problem from the laboratory perspective. Shirley summarized the following information in an official ASCT position statement (published in ASCT News, VIII: 10-11; p. 107; 1987) for presentation to these individuals as well as other media and government representatives.

We gave copies of the ASCT's Professional Brochure and described the duties of the cytotechnologist and emphasized how demanding microscopic evaluation is. We stressed how this important evaluation requires well-qualified individuals with a serious commitment to patient care. We discussed how low salaries make it difficult to recruit qualified individuals into the profession and how this inadequate compensation often diminishes a cytotechnologist's incentive to remain in the profession.

We discussed the dangers of excessive workloads and factors that contribute to this problem, such as low salaries which force cytotechs to work more than one job or screen above the "daily quota" because their payment changes from "salary" to "dollars per case". We pointed out that the primary concern of some laboratories is for profit margin and that these laboratories may consciously or unconsciously ignore the ramifications of this philosophy. We told them how ASCT had examined this problem by surveying its members for their workload experiences, and how this survey had resulted in ASCT's recommended workload figures. We pointed out that a major stumbling block of any workload recommendation is that recommendations are merely advisory and that "advice" cannot insure against the hazards of excessive workloads; enforceable workload recommendations are necessary. We stated that if regulations are going to be considered at the federal level, the ASCT is in a position to provide valuable input into this decision.

We pointed out that there are other factors which also affect diagnostic accuracy and that a primary consideration should be teaching clinicians to collect adequate samples in order to avoid false negative diagnoses.

We went on to discuss how the ASCT is concerned about consumer awareness -how many women really know what Pap smear testing is all about? We emphasized how public education is more important now than ever especially considering the relationship of HPV to precancerous lesions. We told them that ASCT has produced an educational brochure that can be made available to patients through their doctors' offices. We told them that women most likely do not know to ask their doctors about the quality of the laboratory their Pap smears are being sent to and must be strongly encouraged to make this inquiry.

We also had an opportunity to talk to Cindy Pearson of the National Women's Health Network who asked us how their members could be certain their Pap smears would be sent to a reputable cytology laboratory. We said that women should ask their doctors about the quality of the laboratory they use -especially about that laboratory's personnel qualifications and workload requirements- and that ASCT would be willing to share its comprehensive list of standards that reputable laboratories should incorporate in their operation.

Next on the itinerary was a visit to the American College of Gynecologists and Obstetricians (ACOG). Here we emphasized to Shirley Shelton, ACOG's Associate Director of Clinical Practice, how important it is for clinicians to make every effort to submit adequate specimens. We explained that inadequate sampling and poor fixation techniques severely compromise the quality of the Pap smear and significantly increase the risks of false negative diagnoses. We also stressed that if clinicians exercised good judgement in the selection of a cytology laboratory, they can greatly assist cytotechnologists in eliminating or reducing the number of substandard laboratories. Again, ASCT was asked to define the qualities of a high quality cytology laboratory.

In recent weeks, Pat has been invited to speak on a radio station in New York and to attend hearings to be conducted by yet a third investigating committee in Washington. In California, ASCT members and officers Susan Yokota and Elsie Carruthers are coordinating the cytotech effort to support a change in the wording of state legislation which currently reads " a cytotechnologist may not be required to screen above 75 slides per day" to "a cytotechnologist may not screen above 75 slides per day." Susan has been contacted by NBC's *West 57Th* for an interview.

Pat has also learned that laboratory personnel standards in federal regulations may undergo major revisions- that all standards below that of the laboratory director will be dropped- this means standards will no longer exist for the technologists performing the actual testing. ASCT will lodge a formal protest to this proposed change. Your Regional Director will be contacting you about writing individual letters to your state representatives about this. Another piece of legislation which needs our support is the proposed repeal of Section 1123 of the Social Security Act. Repeal of this section would deny the Department of Health and Human Services (DHHS) the right to credential allied health personnel by using proficiency examinations. ASCT is part of an 11-member coalition of allied health organizations who are supporting the repeal of this section.

As you know, articles about Pap smear testing and about the association of sexually transmitted diseases and cervical cancer have been appearing more frequently in women's magazines. ASCT's Public Relations and Education Committee writes formal responses to these articles regarding the accuracy of their information about cytotechnology. Please assist them in this important job by sending any articles you may find to Committee Chairman and President-Elect Louise Newton, 63 Bay Street, Glenn Falls, NY 12801.

ASCT has responded to the concerns many of you have expressed about the College of American Pathologists' Workload Recording Method. The Professional Standards and Practices Committee chaired by Jean Triol presented these concerns to CAP and described how this method does not accurately reflect productivity in the cytology laboratory, and if used by lab administrators to determine personnel needs, may result in seriously under-staffed cytology laboratories. Jean represented cytotechnologists at the CAP meeting held in Michigan in July, 1987 and presented the survey data provided by ASCT members. The CAP Workload Committee appears to be concerned about this problem and asked for additional information which Jean gathered and provided to them. The ASCT asked CAP to consider cytotechnologist representation on the Workload Committee, and they felt this was not feasible at this time.

Many media and government people now recognize the ASCT as a source of information about cytology and are now aware of the interest ASCT has in representing cytotechnologists and the practice of cytopathology. Several of the federal committees investigating the problems surrounding diagnostic accuracy will be conducting hearings to gain further information and ASCT will provide cytotechnologist representation at each of these events. These endeavors have and will continue to require a commitment from the ASCT and its members to contribute a great deal of time, money and effort to meet the current needs of our profession. Each of us must be ready to accept this challenge and unite to advance cytotechnology and cytotechnologists to a position in the health industry that provides the utmost in quality care to every consumer of cytology services. What are you willing to do about it?

Carol Trew

Acknowledgement

Shirley Greening, Patricia Ashton

Senator ADAMS. Dr. Dickerman?

Dr. DICKERMAN. Thank you, Senator.

Senator Mikulski, Senator Adams, I come to speak to you today as the director of a state public health laboratory that does regulate in the area of cytopathology testing, as well as in all clinical laboratory work. And I want to thank you for the opportunity to share in the discussions on critical issues relating to clinical laboratories performing Pap smears to detect cervical cancer.

Indeed, the question I want to address in my segment is what does and what can government do to assure quality in testing.

If we take an overview—and this is merely a superficial overview—of various levels of governmental involvement in this area—for instance, if we look at hospital laboratories, we find that the federal government inspects only in what we call non-JC, or Joint Committee on Hospital Accreditation, laboratories.

In independent laboratories, the federal government is also involved if the bill Medicare—in doctors' offices, not at all. The extent of regulatory oversight in individual states is variable, obviously. To a large extent, reliance for quality assurance programs is placed on voluntary educational organizations, such as the Joint Commission, the College of American Pathologists, and the American Society for Internal Medicine.

The Joint Commission does not conduct proficiency testing per se, but does require participation in a testing program.

Proficiency testing, in my opinion, is the cornerstone of laboratory evaluation. And I will elaborate on that later. There is inspection of the laboratories under the Joint Commission.

The College of American Pathologists (CAP) also carries out proficiency testing with announced inspections, in both hospital and independent laboratories, and conducts proficiency testing in doctors' offices.

The American Society for Internal Medicine (ASIM) does not test hospital or independent laboratories, but does test doctors' offices.

Now, I want to point out that in the case of CAP and ASIM, we are talking about voluntary self-educational organizations. I come from a state that happens to believe that government has a direct role in the enforcement of good laboratory practice. We care about one thing and one thing only, and that is the quality of laboratory care.

Nearly 23 years ago, New York State became the first State in the nation to initiate a certification and licensing program for clinical laboratories. The federal government used the New York program as a model for legislation seeking to develop nationwide clinical laboratory standards—the Clinical Laboratory Improvement Act of 1967.

Since 1972, New York has remained the only state with clinical laboratories exempt from federal/interstate inspection, because our standards are recognized as equal to or more stringent than federal requirements.

Now, our licensure program differs from those of many States which do regulate laboratories, since it does not acknowledge other approval programs, such as CAP's, as an alternative to its own proficiency testing. Thus, hospital-based laboratories are included in the State's inspection and certification program.

Furthermore—and this addresses a very key issue which has been brought up here—New York State regulates laboratories outside the State if they accept specimens collected in New York State, whether these laboratories are located in California, Texas or wherever.

Our aim is not to put laboratories out of business, but to assist them in achieving uniformity and reliability of test results, crucial to the diagnosis and treatment of disease. But the bottom line is the protection of the patient's safety and health. If a laboratory is deficient, it will be subjected to remedial education, and if that does not suffice, the laboratory's license will be revoked. And that is something that government can do and voluntary organizations cannot do.

Under New York State law, directors of all clinical laboratories must hold a Health Department certificate of qualification and each laboratory must obtain a yearly operating permit. Our inspectors visit each laboratory annually to check on staffing, equipment, methodology, quality control, et cetera.

It is integral to our unique history that we place the onus of a laboratory's quality of performance on this certificate of qualification holder. We may have disagreements with other professional societies about this, but we feel that the individual who holds that certificate of qualification is responsible for the total activities in that laboratory.

We are making some changes and going through a review process now, specifically in the area of cytopathology, but traditionally, this has been the mainstay of our policies.

A critical factor in the program is proficiency testing. And now, I should like to address the area of cytopathology, because we do actually oversee about 650 laboratories, of which 250 are cytopathology laboratories.

We inspect these laboratories, but we also can hand-carry tests to each cytotechnologist in a laboratory. If there are 100 cytotechnologists, 100 test sets are sent out, including some five vaginal, two fluid, and two sputum speciments.

All material we send out—and this is another key element—is in the form of a slide, just like those cytotechnologists would routinely get. Results for that slide have been referenced by three outstanding authorities in pathology from both inside and outside the State of New York, and in all cases of a positive finding, these have been backed up by a biopsy. There is thus a surety about the accuracy of the results. We are not talking about, "I think it is good, you think it is good; maybe it is good."

We also evaluate the cytopathologist's performance. And in this sense, we are taking into account a concept which is very, very important, and that is that cytology screening is a team effort, with both cytotechnologists and cytopathologists contributing significantly to the formation of diagnostic reports, although the final interpretation lies with the cytopathologist. This becomes ever so critical in very large laboratory concerns, as we see in California. We must focus on what are the controls in the screening process, what are the interplays between cytotechnologists, cytotechnology supervisors and cytopathologists.

Now, a unique feature of the program, and one I am sure of importance in governmental circles, is that its total cost is recovered from fees assessed on permit laboratories. Fees are based on the total gross receipts of the laboratories, with each paying a proportionate share of program costs based on its gross receipts from New York State testing.

Last year, laboratories in New York State outside of New York City grossed $648,911,000. We are therefore talking about a lot of money in terms of laboratories overlooked in the regulatory process.

I want to come to something that Senator Adams said before. He was talking about restriction of the volume of samples per technologist, and we certainly would want to be able to restrict the number of slides a particular cytopathologist reads.

But I think there are a few steps we have to take before we can get to that point. One is that cytopathology labs should be licensed, and by licensed, we mean they should be inspected, they should be proficiency-tested with real specimens, and if deficient, they should be educated, retested, and if they fail, they should be closed.

So, although I am all for some means of limiting the number of test specimens assigned to individuals during a work day, I'd like to go back to basics, because the rest of the nation has to go back to basics, which comprise inspection, proficiency testing, and some degree of governmental involvement in the performance of a laboratory.

At this point, we have some specific suggestions, but I do not know if you want them now or if you want them later, in the context of the federal program.

Senator **ADAMS**. Doctor, why don't you submit those to us, because Senator Mikulski and I and a number of others will be working on legislation, and I know that Senator Mikulski will want to go to some questioning, and I do, too.

But please, go ahead with your testimony.

Dr. **DICKERMAN**. I would just like to say one thing finally, and that is, that it can be done. It can be done. It takes a lot of effort. It takes a lot of work. It takes a lot of intermeshing of activities between the federal government and state governments, but it can be done. The program is not cheap, but I think in terms of human life and human resources and what is at stake, it is cheap. But it can be done with the proper expertise and the proper energy.

Thank you.

Senator **ADAMS**. Thank you, Doctor.

[The prepared statement of Dr. Dickerman follows:]

Testimony of Herbert W. Dickerman, M.D., Ph.D.
Director, Wadsworth Center for Laboratories and Research
New York State Department of Health
January 28, 1988
Senate Committee on Labor and Human Resources
"Cancer Detection in Women"

Thank you for the opportunity to share in discussions on critical issues relating to clinical laboratories performing Pap smears to detect cervical cancer. The quality of analyses performed by clinical laboratories, in cytopathology and other fields, must be assured in order to prevent deterioration of health care of our citizens. Because of its history as overseer of laboratories in the State of New York, I, as Director of the Wadsworth Laboratories of the New York State Department of Health, wish to review the laboratory regulation issues involved in "Cancer Detection in Women".

The New York State Program

Nearly twenty-three years ago, on July 1, 1965, New York became the first state in the nation to initiate a certification and licensing program for clinical laboratories. The enabling legislation was the State's Laboratory Improvement Act, enacted in 1964. The federal government used New York's program as a model for legislation seeking to develop nationwide clinical laboratory standards — The Clinical Laboratory Improvement Act

(CLIA) of 1967. Since 1972, New York has been the only state where clinical laboratories are exempt from federal interstate inspection, because our standards are recognized to be equal to or more stringent than federal requirements.

New York State's licensure program differs from those of many states which do regulate laboratories since it does not recognize other approval programs as an alternative to its proficiency testing; thus, hospital based-laboratories are included in the inspection and certification program. Further, New York regulates laboratories outside the State if they accept specimens collected in New York State.

The regulatory program is carried out by the Wadsworth Center for Laboratories and Research of the New York State Department Of Health, which sets standards for laboratory testing and inspects, tests, and licenses hospital laboratories and independent laboratories in addition to out-of-state laboratories doing business in New York State. Additionally, Medicare surveys are conducted by the Wadsworth Center for laboratories located in New York City, which has a separate regulatory program.

The aim is not to put laboratories out of business but to assist them in achieving uniformity and reliability of test results, crucial to the diagnosis and treatment of disease. But the bottom line is protection of patient safety and health - so if a laboratory is deficient, it will be subjected to remedial education, and if that does not suffice, that laboratory's license will be revoked.

At the present time 635 laboratories possess permits in a full range of clinical laboratory specialties. In its regulatory program, the Wadsworth Center has also demonstrated its ability to deal with rapid changes in laboratory technology. Within six months of FDA approval of testing kits, the Center implemented inspection and proficiency testing for Maternal Serum Alpha-fetoprotein and Human Immunodeficiency Virus.

Under State law, directors of all clinical laboratories must hold a Health Department certificate of qualification, and each laboratory must obtain a yearly operating permit. Health Department inspectors visit each laboratory annually to check on staffing, equipment, methodology, quality control, cleanliness, record-keeping and general effectiveness.

Proficiency testing is a vital part of the laboratory improvement program. Test specimens are mailed and/or carried to each clinical laboratory for analysis within a specified period. A detailed description of the New York State program is attached. Laboratories failing to meet standards must improve proficiency through training, successfully pass retesting, or cease operation in categories failed. State-sponsored training courses in the form of seminars, workshops and lectures are given periodically. Invited laboratory personnel are brought in for "in-house" training, and inspectors provide on-site instruction during their inspection visits.

The New York State program is located in the Wadsworth Center for Laboratories and Research of the New York State Department of Health. The Center, which has both clinical and environmental responsibilities in areas of service, research and regulation, provides scientific and technical support to clinical and environmental laboratory improvement programs. Each proficiency testing specialty section is headed by a physician or doctoral-level expert in the field. In addition to their public health service and research responsibilities, the directors provide scientific oversight for the proficiency testing program in their area of expertise.

The Environmental Laboratory Approval Program (ELAP) which began in 1986 is designed to be the most rigorous in the country, as is the clinical laboratory program. Building on experience gained in the clinical laboratories, ELAP produces its own semiannual proficiency testing materials, and conducts annual inspections. The laboratory is therefore able to meet the specific needs of the State for quality environmental testing. Future plans for this unit include closer integration with the clinical program in the areas of occupational health and environmental toxicology.

Another unique feature of the program is that its total cost is recovered from fees assessed on permit laboratories. Fees are based on the total gross receipts of laboratories, with each laboratory paying a proportionate share of the cost of the program based on its gross receipts from New York State testing. Last year, laboratories outside New York City reported gross receipts of $648,911,051.

The cytopathology program is directed by Doris N. Collins, M.D., M.I.A.C., who developed a nationally acclaimed program in proficiency testing of cytopathology laboratories including the screening cytotechnologists, their supervisors, as well as the attendant pathologist.

The following excerpt from the 1986 paper "Proficiency Testing in Cytology in New York, Analysis of a 14 year Program" by Dr. Collins and Domiciano P. Patacsil, MD (Acta Cytologica Vol. 30, No. 6), describes the design and evolution of the program:

"At its inception in 1968, testing was limited to cytotechnologists and was therefore administered to only about half of the laboratories in the state. In 1971, a more comprehensive evaluation was introduced, which included testing laboratories where no cytotechnologists were employed. The expanded program was designed to measure through internal and external evaluation the laboratory's total performance, based on its daily practice of exfoliative cytology."

"Cytology is a team effort, in which both cytotechnologists and cytopathologists contribute significantly to the formation of diagnostic reports, although the final interpretation lies with the cytopathologists. Thus it is important to test each individual's proficiency since the laboratory's performance is only as good as that of its weakest member. On-site testing by laboratory consultants with hand-carried test material was deemed essential, as was computer-based acquisition, storage and analysis of the test results."

"When the program was further expanded in 1978, testing of each individual laboratory was scheduled biennially due to the increased demands placed on the laboratory consultants. Approximately half of the permit laboratories have been tested each year. The scheduling takes into account the laboratories' previous performance as well as the number of cytotechnologists they employ. Biennial testing has allowed ample time to test and retest laboratories and has avoided the problem of carry-overs into succeeding test years."

"Varied case material has been introduced into the test sets, permitting a gradual acceptance of changes in test composition in successive years. Prior to the 1980-1982 test period, the laboratories were tested on seven cervicovaginal and three sputum smears. In 1980-1982, two of the cervicovaginal smears were replaced by two body fluid smears, but the interpretation of these body fluid smears was disregarded in the scoring for that period. Therefore, in the 1980-1982 test period, laboratories were rated only on eight smears (five cervicovaginal and three sputum). In 1982-1984, laboratories were tested and rated on ten smears (five cervicovaginal, two body fluid and three sputum)."

"Test specimens were derived from various New York State and out-of-state sources. Most were contributed by pathologists; the rest were from cases in our laboratory files. A confirmatory biopsy or autopsy was performed for all suspicious or positive specimens. For all sources of negative cervicovaginal specimens, three consecutive annual negative smears were required. Negative sputum and body fluid specimens required a negative surgical biopsy and a subsequent autopsy showing no malignancy. Final selection of all specimens was contingent on complete agreement of interpretation by at least three reference laboratories, which also evaluated the suitability of the smears for testing based on adequacy of cellular content, satisfactory staining quality and degree of difficulty."

"The number of tests administered to a laboratory is determined solely by the number of cytotechnologists it employs. Each cytotechnologist, whether full-time or part-time, receives a test set of ten slides. A laboratory with a single cytotechnologist is given one test set, regardless of the number of cytopathologists on the staff. A laboratory that does not employ cytotechnologists, i.e., where the cytopathologist does his or her own screening and interpretation, is given only one test set. Thus, for test purposes, each laboratory can be categorized as a single-test laboratory (STL) or a multiple-test laboratory (MTL)."

"Completed tests are returned immediately to the Laboratory of Anatomic Pathology and Cytology, where they are manually corrected and computer-encoded. Participating laboratories are notified by letter of their performance and are scheduled for retesting if necessary. Laboratories failing the first test are retested. If performance on the second test is unsatisfactory, the cytopathologist must participate in a five-day cytology review course before a third test is scheduled. Failure on the third test necessitates a ten-day review prior to a fourth and final test. (The opportunity for a fourth test was offered in 1972-1973 and resumed with biennial testing in 1978.)"

"Failure on the fourth test results in withholding of the laboratory's permit for the next test period. No further test is offered until the responsibility for signing diagnostic reports is shifted to another qualified cytopathologist. The laboratory is then restored to its normal test schedule."

"Cytotechnologists screen the test slides and determine the need for further examination by the cytopathologist. Smears considered to have abnormal cells are marked and passed on the cytopathologist, as indicated by a "refer to pathologist" on the answer sheet. Negative specimens are likewise indicated on the answer sheet; these also are given to the cytopathologist, who has the option of checking the slides and agreeing or disagreeing with the screener's assessment. The cytopathologist makes the final diagnosis on each specimen, which can be negative, suspicious or positive. The cytopathologist's answers are rated as correct, incorrect (false negative or false positive), acceptable or invalid; on this basis, the laboratory is graded. Satisfactory performance is based on the number of errors not exceeding the total number of slide sets examined by a laboratory (90% accuracy)."

"The answer category "acceptable" allows some in-exact responses to be considered correct. In particular, a response of "suspicious" is rated acceptable even if the test slide is a referenced positive smear. A "suspicious" response is rated incorrect, however, when the test material is negative."

"The cytotechnologist's performance does not directly affect the laboratory's rating. To allow deficiencies to be corrected internally, a summary of the test performance of each cytopathologist and cytotechnologist is sent to the laboratory director or administrator at the end of each test period."

"A comprehensive on-site survey of the laboratory's internal quality control and its compliance with regulatory standards covering facilities, personnel and methodology is undertaken annually. The standards are those prescribed by New York State health laws, the Centers for Disease Control and the Health care Financial Administration. Deficiencies are cited, and laboratories are encouraged to rectify these prior to reinspection. Suggestions and guidelines are offered to deficient laboratories during postinspection reviews conducted with the laboratory director and/or administrator. Noncompliance with these standards may result in withholding of the laboratory's permit regardless of satisfactory test performance."

"Continuing education is essential in maintaining a high level of professional performance. In addition to workshops and seminars, a "case of the month" is distributed to all licensed cytology laboratories in the state. Each case consists of photomicrographs showing cytologic and histologic findings, plus a clinical history, discussion and bibliography. Additional training is required for deficient laboratory."

The full text of the article is attached.

Other Regulatory Issues

New York does not claim expertise in the regulatory programs of other states; nor do we have direct knowledge of the rigor of the Interstate Laboratory Program established under CLIA, as New York has been exempt since 1972. Similarly, since we do not use peer review programs such as those of the College of American Pathologists or the Association of Bioanalysts, we do not have extensive information on these programs. There are, however, some general observations that warrant mention.

The Federal Health Care Finance Administration (HCFA) program, by regulating only independent laboratories which bill Medicare leaves many facilities unregulated.

While New York is not affected, the HCFA Budget Call Letter dated July 7, 1987 established a target of 60% coverage for routine surveys of independent Medicare laboratories, further diluting the benefits of the program.

In hospitals which have Joint Commission (JC) approval, the laboratories are exempt from Federal oversight. Only in hospitals which have lost JC approval is HCFA oversight exercised. In New York State this represents only 3 of 277 hospitals. To our knowledge, JC has not revoked approval of a hospital based on deficiencies in its laboratory.

Our experience with JC laboratory surveys indicates that their emphasis has been on frequency of proficiency testing not its rigor or difficulty. Nor does JC require that a laboratory "pass" proficiency testing, only that it participate. Surveys of testing procedures are similarly superficial in scope or detail.

The Centers for Disease Control recently sent a proposal to HCFA that sets minimum standards for proficiency testing that arbitrarily calls for quarterly proficiency testing. Yet there is no evidence that the frequency of testing is better at identifying problem laboratories than semi-annual or annual repetition. The proposal is incomplete as it omits oversight of Pap smear tests as well as other categories. Worse, from a regulatory point of view, is that the failing grade would usually be set at values beyond 3 standard deviations. This results in failure of only 1% of examined laboratories. Our experience indicates more rigorous standards are appropriate. The CDC responded to this criticism as follows:

"Several comments were received that support the continued use of a 2-standard-deviation limit to identify laboratories that are on the fringe of acceptable performance. Most of these comments came from groups who have had experience in using a 2-standard-deviation limit to identify laboratories in need of improvement. The purpose of the uniform program is not to educate or improve laboratory performance but to protect the public from laboratory results that are so much in error that they might adversely affect patient care. Therefore, the focus of this program is on laboratories who are consistently providing inaccurate or imprecise results, not on those that are providing an occasionally deviant result."

Rigor of testing standards does not discriminate against the laboratory producing an occasionally deviant result but, in multiple analyte testing, does identify the chronically deficient laboratory.

An additional weakness is that the CDC proposal exempts Pap smears as well as virology, histology, urinalysis, hemoglobinopathy, newborn screening, cytogenetics, drugs of abuse, and oncofetal antigens from proficiency testing. This was discussed as follows in the proposed guidelines:

"The Task Force considered each of these areas for inclusion in the program. They were not included in this proposal, however, either because the error rate has been found in the CDC program to be extremely low (urinalysis), or because there were concerns about obtaining suitable sample materials, or because of the lack of a professional consensus about what should be evaluated or how performance should be assessed."

New York is very concerned that its current program, which does not have quarterly testing in all categories, may not be recognized by HCFA as meeting the minimum standard. This will result in either redesign of the program, to provide quarterly testing, despite lack of documentation that quarterly testing is necessary or for New York State laboratories to supplement proficiency testing with quarterly programs.

Medicare inspections, which are conducted by the Center, in conjunction with the regular state annual inspection, place too much emphasis on paper documentation of personnel qualifications and time limits and not enough on quality. A laboratory can be quickly decertified for failure to pay the required permit fee or submit documentation about personnel yet a laboratory can continue testing despite serious violations of quality control requirements until an administrative action is completed. Administrative proceedings can be lengthy. This results in marginal laboratories continuing to bill Medicare for long periods of time.

Many clinics, including rural health centers, which are required to provide certain tests to receive Federal approval, are under no regulatory oversight at all. They are not required to participate in either the State or HCFA program. Other clinics also fall into this void, many of which obtain Federal Funds. The Center is attempting to address this problem and expects to have a program in place shortly. We can only ask, what is the quality outside New York State? Other glaring deficiencies in Federal regulation include employee drug testing and laboratories performing tests for insurance underwriting. Regardless of the use of the test, the Center believes that everyone is entitled to quality testing. The current patchwork does not assure this.

Peer review programs such as those administered by the College of American Pathologists and the Association of Bioanalysts provide a valuable service in quality assurance. They are not regulatory nor are they designed to be. Their success is based on voluntary participation by laboratories which want to do the best job possible. But this omits the crucial ingredient of public accountability, that the laboratory service offered to the public is of the highest quality and that those laboratories which do not comply with this standard will not be permitted to operate.

Another problem is lack of quality assurance of those laboratories located in physicians offices.

I understand that HCFA will require some regulation of physician office laboratories performing 5000 or more tests by January of 1989. I have not seen the language of this requirement, as yet, however if the criteria for inclusion is 5000 tests billed to Medicare, physician office laboratories serving young women and children will continue to be unregulated.

Of special interest to this committee is the growing phenomenon of Pap smears being read in physician offices. The Center, which is currently prohibited from regulating tests in physician offices, is proposing legislation to determine the extent and variety of such testing in New York State and develop means for proficiency testing and inspection of those operations.

While we are concerned with physician-office testing overall, the area of Pap smears is critical. If some certified laboratories under some level of regulation are missing cervical cancer, what is happening in the doctor's office?

Federal Action

New York believes that regulation of laboratories belongs at the State level, since government closest to the regulated parties is most effective. The Federal government should take steps to stimulate state regulation, one of the original goals of the Clinical Laboratory Improvement Act. All laboratories testing human specimens, including hospitals, clinics, doctor offices, employee drug testing programs, and insurance companies should be regulated. Encouragment could be provided through grants to States for the development of the programs, with on-going support provided through assessments on the laboratories, as in New York.

Initiatives to educate physicians and other providers about correct technique in collection of cervico-vaginal smears and the limitations of the tests and the public as to their responsibilities and right-to-know where their tests, not only Pap-smears, are being sent.

A national direct-billing law, similar to New York's which requires that laboratories bill the patient or the insurance carrier rather than the doctor would eliminate incentives to choose laboratories based on costs and assure that the public knows where the tests were done.

One of the most critical areas is the shortage of qualified cytotechnologists as well as other medical technologist and the closure of many of the programs. Health manpower development funds directed to cytotechnologist and medical technologist programs are critically needed. Finally, action is necessary to improve the status, advancement, and wages of cytotechnologist and medical technologist to keep them in the field. Wage strategies should be geared to discourage payment by the slide or case and moonlighting. This can only happen when the salaries are adequate for these positions.

Finally, we will not fail in this arena as long as quality of care in the laboratory, no less than in the hospital, clinic or office, is maintained despite countervailing demands of cost.

Senator ADAMS. I have this question, or maybe it is a statement, and Dr. Dickerman you can comment on it, and the others, too, because you represent a broad spectrum.

One, I agree with you, Dr. Schulman, we certainly do not want to in any way inhibit or stop women from proceeding with Pap smears, because we have got a problem. Far and away the advantages outweigh the disadvantages, and I think we all are in agreement on that.

But two things are occurring which make a difference, and I would like you to address them, and you can, Dr. Schulman, and then Dr. Dickerman, or whoever else.

Dr. Hasselbrack talked about the fact that we have a great deal more potential transmission now which is exacerbating the size of the problem. Dr. Dickerman talked about a thing that is concerning me, which is that we have had a great advance in technology so that doctors and the whole medical profession tend to shift things over into a technical area—in other words, a whole series of lab tests, and this is done as a part of an advancing technology.

But we have got a gap here that Ms. Ashton has so clearly identified, of having a handcraft in the middle of this technology that is life-threatening. And I am very much prepared to go with licensing. The reason I mention the handcraft part is, as we are drafting and going into this, how do we cover the Pap smear area, where it is labor-intensive, and unless we establish some kind of baseline for this, the pressure is completely on the cytotechnologists and the cytopathologists within this large technical laboratory to be a "lost leader" or a gap that we have to look at in some way because it is not a machine. And most people do not know that. They feel that all of these things go into some huge technical device, and out of that spews an absolutely accurate result.

So I would like your comment, Dr. Dickerman or Ms. Ashton, or any one of you who would like to comment on how we handle that gap.

Dr. HASSELBRACK. Senator Adams, I would like to say that I believe the women of America should be more assertive, ask more questions, and confront their clinicians with the Pap test problem as it exists now, because clinicians are presently driving the system. They are the ones, and unfortunately, Government-supported clinics as well, who are driving the "Pap mills".

I would also like to see a greater shift from intervention to wellness, from treating disease to wellness. Therefore, we should be asking the primary care physician to act as a public health official would act in controlling a virtual epidemic of sexually transmitted disease.

Some clinicians are reluctant to describe cervical precancer as an epidemic of sexually transmitted disease, but certainly, we have to take a generic approach to this problem, not only of cervical precancer, but of AIDS and some 30 other sexually-transmitted diseases.

It is the clinician that must effectively engage the mind of a patient. We have no magic bullet with AIDS; and although cancer of the cervix is a treatable disease, we have to start upstream; we have to educate women and men to assume greater responsibility. Without the magic bullet, we must ask physicians to return to the art of medicine and convince individuals that they must alter lifestyle behavior. I applaud the American Cancer Society for creating that focus. Looking at the immediate problems in the "Pap smear" industry", we have to deal principally with the "Pap mill" phenomenon; then, secondarily, we must establish uniform quality validation procedures for laboratories engaged in the practice of cytology.

Senator ADAMS. You wanted to say something, Dr. Schulman. I did not mean to cut you off.

Dr. SCHULMAN. That is quite all right, Senator. I simply want to emphasize that despite what has been said, our most accurate method for early detection of cancer of the cervix in a curable phase is still the Pap smear. And the thing that I would like to emphasize is the fact that the Cancer Society says that this should be done on a yearly basis—if something happens so that one of them does not get picked up the first time because of some error or something, you are doing it the next year.

We believe it takes a number of years. We can find many of these in a precancerous phase, and it may take a number of years for them to go on to become more significant.

Senator ADAMS. Give us a time period—and others can comment—what you are saying is that women should ask for a second opinion, or should inquire. But I am getting from you also that we are getting a much faster development period for cervical cancer. Is that why the Cancer Society said do it at least three years in a row?

Dr. SCHULMAN. At least three years in a row, and if all three years—and examination, not just the Pap smear—and if all three years are perfectly okay, then it is up to the physicians to decide whether they should or should not have it, and how regularly thereafter.

But the point of the matter is that in three years, if there is anything there of a precancerous nature, it should be picked up.

Senator ADAMS. Senator Mikulski?

Senator MIKULSKI. Thank you, Senator Adams.

I thank all of the panelists for testifying. My questions will go to Ms. Ashton and then to Dr. Dickerman.

But before I do, I have to say something about everybody giving more responsibility to the women. Women have assumed responsibility for their health care. Women discipline themselves every day by cutting back on smoking. The mere fact that a woman goes for a Pap smear indicates that she is willing to take consumer responsibility.

And I agree with you, Dr. Hasselbrack, a woman should ask questions; or you, Dr. Schulman, to get a second opinion.

But women cannot bring about systematic change. It is the United States Government and physicians among themselves, shaking, rattling and rolling the system against greed and callousness that can do it.

I can ask my doctor questions, but that is a temporary solution to an individual problem. When I get on an airplane, I assume that I am safe because there is Federal regulation; I do not go to the individual mechanic to see if they checked the sparkplugs.

We need systemic change; we need systemic regulation, and we need not only Government activity, but quite frankly, physicians in this country have to speak out against greed and callousness within their own profession. And I really, really must insist upon that, which takes us to my other point.

I am sick and tired in some ways of the blame being put on the victim—the victim. We are being medically mugged by these laboratories, and I am just kind of tired of it.

Having said that, Ms. Ashton, I want to know how much cytotechs are paid.

Ms. ASHTON. This varies geographically, Senator Mikulski, from, according to the statistics I have, a low of $12,000 per year in some parts of the country up to a starting salary of $22,000 in other parts of the country.

Senator MIKULSKI. And what is the training of an adequate, qualified, certifiable cytotech?

Ms. ASHTON. Thank you for asking that question. I think that is very important. Cytotechnologists have a minimum of two years of undergraduate education with specific course loads in the biological sciences. After that, they spend a full 12 months intensively being trained in programs of cytotechnology. These programs are accredited by the American Medical Association and are conducted mainly in hospitals, and now in increasing number, in universities.

Following this training, the majority of cytotechnologists sit for a National Registry Examination before they are employed, or at least sit for this examination shortly after they begin employment, as long as they are Registry-eligible.

A key change has occurred in the last year, in that now, all programs in cytotechnology must admit students who already possess a baccalaureate degree or must award such a degree. This has been a change in the Essentials for the schools of cytotechnology.

I happen to have received a degree from a college in your state, Goucher college, before I trained at Johns Hopkins Hospital, in cytotechnology. So I have had five years of training relating to detection of cancer.

Senator MIKULSKI. That is quite a technical background. Thank you.

Dr. Dickerman, the New York program is being held up as a national model. The criticism is that doing some of your recommendations would be expensive. Could you tell us how much the New York program costs and how is it paid for—out of general revenues, or is there a tax on the labs, or do you pay a surcharge on a Pap smear?

Dr. DICKERMAN. Well, it does cost us about $2.5 million per year to accomplish the total laboratory certification program. Now, this includes everything from lead analysis to cytopathology, chemistry and bacteriology.

I could not single out cytopathology figures for you. Between inspectors and administrators, the program comprises roughly about 30 to 40 people, and it is backed up by, I am proud to say, the premier state health laboratory in the country, with a formidable array of talent both in research and in service laboratories.

The particular program I am representing here today has been directed by Dr. Doris Collins, M.D., since 1964, and much of it has been described in the medical literature, in *Acta Cytologica*.

I think it is feasible to fund a program as we did it; actually, the Legislature forced us to do it so. Approximately three to four years ago the Legislature decided to assess the regulated parties rather than the State General Fund. It has worked; there are obviously some differences with the laboratories about fees and what they are paying, and that will go on for a period of time. But it appears to be the intent, at least within New York State, to keep this as an industry, as you would call it, a fee situation rather than resort to general taxation.

I do not think this is how a program can be approached nationally in the beginning. I think you are going to have to consider some federal support to those states without a program until they can establish themselves, in order to be able to do what we have done.

Senator MIKULSKI. Thank you.

I only have one last question, Doctor, and that is related to the concept of proficiency testing. Of course, I presume that you would demand certification first. And my question then was on the way you talked about executing it.

Are you talking about lab-specific proficiency testing, or are you talking about someone like Ms. Ashton's counterpart, say in Maryland or so on, where you would pass one test and be able to work in any laboratory around the State?

Dr. DICKERMAN. No, no. We license the laboratory, and that means we test the cytotechnologists within that laboratory. We look at the professional credentials of each technologist who is in that laboratory, but the lab carries the onus for licensure. If the lab does not make it, the lab is closed. The cytotechnologist does not bear the brunt of our particular regulations.

Senator MIKULSKI. Thank you, Doctor. We look forward to getting your recommendations in writing. I know that Senator Adams and I are going to work on the interstate issues.

We also would like suggestions for model legislation, perhaps to discuss at the National Governors Association, and we welcome that.

I guess what is disturbing to me is we always hear about cost, and yet we are willing to license beauty shop operators and have the money to do that, but we don't have the money to regulate and license someone in laboratories.

Ms. ASHTON. May I comment on that, Senator Mikulski? This has always seemed rather ironic to me, that the person who may wash your hair in a beauty shop must possess a license, but it is not required in order to screen or examine a Pap smear for cancer detection.

Dr. DICKERMAN. I have one more observation. I certainly don't want to give Dr. Schulman the impression that we think that the Pap smear is an intrinsically horrendous test and that it is not being performed well. We definitely back the American Cancer Society's effort to have women tested.

I would like to bring up one concern, which has arisen from our surveys. If a smear does not constitute an adequate specimen, we would like the gynecologist or the physician in charge to call the patient back. This is time-consuming, but very necessary.

We cannot allow the laboratory or the physician to ignore the inadequate specimen. We certainly cannot allow the laboratory to neglect sending back a suspicious slide because they do not want to get people out-of-kilter about it.

Senator **ADAMS**. Thank you, Dr. Dickerman.

We want to thank all of you on the panel. I want to announce at this time that the record will remain open for written comments from interested parties for 14 days. We appreciate very much your comments. We look forward to your recommendations so that we may address this problem, which we believe you have helped educate the public, but more importantly, that you will help us in trying to meet the problem.

[Additional material supplied for the record follows:]

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WASHINGTON OFFICE

NEWS RELEASE

FOR IMMEDIATE RELEASE:
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ASCP RECOMMENDS ACTIONS TO ASSURE QUALITY PAP TESTS

Recently public attention has focused on the quality of cervical/vaginal Papanicolaou (Pap) smear tests used for the early detection of cancer in women. The Pap smear test has been primarily responsible for a reduction in the mortality rate for cervical cancer by more than 70% over the past 40 years.

To assure the early detection of cervical cancer, The American Society of Clinical Pathologists (ASCP) recommends that, all women who are, or have been sexually active, have an annual Pap test, screened by qualified personnel, unaffected by financial disincentives.

A cervical/vaginal (Pap) smear test should be performed annually because:

1) the natural history of cervical malignancies is unpredictable.
2) there is a small, but irreducible, false negative rate.
3) on the average, patients tend to do less than their physicians recommend.
4) the physician may not be aware of all of the patient's risk factors.
5) it is illogical to recommend a general annual physical examination for the purpose of detecting abnormalities that fails to include one of the procedures that is mostly likely to detect a curable disease.

To assure quality in the performance and interpretation of the Pap smear test:

1. screening of a cervical/vaginal (Pap) smear should be performed in an accredited laboratory by certified cytotechnologists.

2. reasonable limitations on the daily volume of cytological smears examined and the number of hours worked by each cytotechnologist should be based on recommendations of professional organizations.

3. cytology screening should be performed under the supervision of a certified pathologist or cytopathologist who has appropriate experience in this field.

4. the pathologist who directs the cytopathology laboratory should establish and administer an on-going quality assurance program with standards recognized by national professional organizations.

5. Pap smear tests should be available to all patients at a reasonable cost.

6. the strong financial incentives to perform low quality or substandard pap smears should be eliminated. Monies spent for Pap smear testing should be used for those lab services.

ASCP is a nonprofit medical specialty society organized for education and scientific purposes. Its membership numbers over 45,000 board-certified pathologists, other physicians, clinical scientists and certified technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and as the leading organization for the certification of laboratory personnel. ASCP's certifying board registers over 140,000 certified laboratory professionals annually.

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Senator ADAMS. Thank you all very much. The Committee will stand in recess.

[Whereupon, at 1:06 p.m., the Committee was adjourned.]

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